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)

February 2013

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 preparingsubmissions to HTA advisory committees. It is intended to help those whoprepare 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 amore 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

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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](#obsolete))

**Absolute risk** (see [risk, absolute](#riskabsolute))

**Absolute risk difference** (see [risk difference](#riskdifference))

**Accuracy** (see also [validity, trial or study](#validitytrialorstudy))
The degree to which a [measurement](#measurement), or an <#estimate> based on measurements, represents the true [value](#value) of the [variable](#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](#costacquisition))

**Admitted patient** (see [patient, admitted](#patientadmitted))

**Adverse outcome** (see [outcome, adverse](#outcomeadverse))

**Adverse reaction** (see [reaction, adverse](#reactionadverse))

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

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

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

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

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

**AHMAC**
Australian Health Ministers’ Advisory Council

**Analysis, cohort-expected value** (see [analysis, deterministic](#analysisdeterministic))

**Analysis, conjoint** (see also [discrete choice experiment](#discretechoiceexperiment))A survey method of [data](#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](#clinicalmanagementalgorithm))A technique that formally identifies the options in a decision-making process, quantifies the probable [outcomes](#outcome) (and costs) of each, determines the option that best meets the objectives of the decision maker, and assesses the [robustness](#robustness) of this conclusion.

**Analysis, deterministic**A [decision analysis](#decisionanalysis) that always returns the same result for a specified set of [inputs](#input).

**Analysis, economic** (see also [economic evaluation](#economicevaluation); [analysis, financial](#financialanalysis))
An umbrella term covering botheconomic evaluation and financial analysis.

**Analysis, financial** (see also [cost, financial](#financialcost))
A procedure for comparing only the financial costsand cost offsets of competing [health technologies](#healthtechnology), rather than comparing their clinical and [economic cost](#economiccost) and [benefit](#benefit). Also called a [budgetary analysis](#budgetaryanalysis).

**Analysis, incremental**A measure of how much extra a proposed[health technology](#healthtechnology) costs to produce an extra unit of [outcome](#Outcome) compared with an available health technology (or no clinical management) for a specified [indication](#indication). It is calculated by dividing the difference in the [net costs](#netcost) 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](#healthtechnology) shares, rather than substitutes for, existinghealth technologies, such as the partial cost changes when the proposed health technology is likely to change current patterns of [resource provision](#resourceprovision) to an incomplete extent.

**Analysis, marginal**An analytical technique that examines the extra costs and [outcomes](#Outcome) caused by producing and providing one extra unit of a [resource](#resource).

**Analysis, primary** (compare with [analysis, secondary](#secondaryanalysis))The analysis of the [primary outcome](#primaryoutcome) that is used in the prespecified [sample size calculation](#samplesizecalculation) (or [power](#power)).

**Analysis, probabilistic sensitivity**A means of representing [parameter](#parameter) and stochastic [uncertainty](#uncertainty) in the results of an [economic evaluation](#economicevaluation). In a [decision analytic model](#decisionnanalyticmodel), [probability distributions](#probabilitydistribution) are assigned to the uncertain parameters and are repeatedly evaluated (such as using a [Monte Carlo simulation](#montecarlosimulation)).

**Analysis, regression**Given [data](#data) on a dependent [variable](#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](#sensitivityanalysis), involving the simultaneous substitution of [parameter](#parameter) [values](#value) and assumptions associated with the [base case](#basecase) to apply the model to other [circumstances of use](#circumstancesofuse).

**Analysis, secondary** (compare with [analysis, primary](#primaryanalysis))Other analyses of the [primary outcome](#primaryoutcome); any analysis of a [secondary outcome](#secondaryoutcome).

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

**Analysis, subgroup** (see also [subgroup](#subgroup))An analysis in which the effect of a [health technology](#healthtechnology) is evaluated in a subgroup of a [study](#study) or [trial](#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](#economicevaluation), including a [cost-benefit analysis](#costbenefitanalysis), which takes into account a broader array of consequences in terms of costs and [outcomes](#outcome) than the [base-case](#basecase) analysis.

**Analysis, truncated time-to-event**[Time-to-event data](#timetoeventdata) where the [trial](#trial) [follow-up](#followup) is insufficient to record all events.

**Analysis, utility**A method of measuring [outcomes](#outcome) in terms of the [preferences](#preference) or utilities that individuals express for specific [health status](#healthstatus)es or [health outcomes](#healthoutcome); it provides a common unit that can be used to compare different types of outcomes under conditions of [uncertainty](#uncertainty).

**Analytical plan, focused** (see also [translation/translated)](#translationtranslated)
A plan for the conduct of a [premodelling study](#premodellingstudy) to address a translation issue that focuses on the objective and presentation of the study, including details about [data](#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](#translationtranslated); [validity, trial or study](#validitytrialorstudy); [validity, external](#externalvalidity))An assessment of the extent to which participants and [circumstances of use](#circumstancesofuse)in a [trial](#trial) or [study](#study) are similar to the proposed population for the [health technology](#healthtechnology) (including the [baseline risk](#baselinerisk) 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](#PBS)[restriction](#restriction) or [MBS](#MBS)item descriptor.

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

**Appraisal (HTA)** (see also [assessment](#assessment); [evidence](#evidence))
The deliberation of the [HTA advisory committee](#HTAadvisorycommittee), comprising a consideration of the [assessment](#assessment) of the [evidence](#evidence)relating to the proposed[health technology](#healthtechnology), 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](#appraisal))
The compilation, analysis, presentation and scientific [critique](#critique) of the best [evidence](#evidence)available for consideration by the [HTA advisory committee](#HTAadvisorycommittee) to address the question of public funding for a proposed [health technology](#healthtechnology).

**Assessment, clinical** [PLAC]An evaluation by a clinical expert of [evidence](#evidence) provided in an [application](#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](#MSAC) or for MSAC to consider varying an existing medical service on the [MBS](#MBS).

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

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

**Assessment group** (see [group, assessment](#assessmentgroup))

**Association** (see also [causality](#causality))
A [statistical](#statistic) dependence between two or more events, characteristics or [variables](#variable). An association exists when the [value](#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](#attributablerisk))

**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)](#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](#therapeuticgood) that is entered in the [Australian Register of Therapeutic Goods (ARTG)](#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)](#diagnosisrelatedgroup) classification system, developed by the Australian Government and updated every two years.

**Australian Register of Therapeutic Goods (ARTG)**
The register of [therapeutic goods](#therapeuticgood) 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](#therapeuticgood) that is entered in the [Australian Register of Therapeutic Goods (ARTG)](#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](#vaccine) available in Australia, including those on the [National Immunisation Program](#NIP)*.*

**Authority-required benefit** (see [benefit, authority-required](#authorityrequiredbenefit))

**Authority-required benefit (streamlined)** (see [benefit, authority-required (streamlined)](#authorityrequiredbenefitstreamlined))

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**Base case**
The results of an [economic evaluation](#economicevaluation) using the projected most likely [values](#value) against which the results of [sensitivity](#sensitivity) analyses are compared.

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

**Baseline risk** (see [risk, baseline](#baselinerisk))

**Before-and-after study** (see [study, before-and-after](#beforeandafterstudy))

**Benchmark** (see [frame of reference)](#frameofreference)

**Benefit** **(**compare with [outcome, health](#healthoutcome))
An advantage or improvement caused by a [health technology](#healthtechnology), or the desired [outcome](#outcome) of using a health technology.

**Benefit, authority-required** [PBAC]
A medicine (or proposed prescription in relation to a medicine) listed in the [PBS](#PharmaceuticalBenefitsSchemePBS), that is restricted and requires [prior approval](#priorapproval) 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](#authorityrequiredbenefit))
A medicine listed in the [PBS](#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](#prosthesis)on the [Prostheses List](#PL)to a privately insured patient with appropriate cover as part of [hospital treatment](#hospitaltreatment) or [hospital-substitute treatment](#hospitalsubstitutetreatment). This same amount applies to all prostheses listed in the same [group or subgroup](#group), and with the same [suffix](#suffix).

**Benefit, incremental**The absolute difference between the [benefits](#benefit) of alternative [health technologies](#healthtechnology) of the same [medical condition](#medicalcondition), disease or disorder.

**Benefit, marginal**The extra [benefit](#benefit) caused by providing one extra unit of a [resource](#resource).

**Benefit, Medicare** (see also [service, clinically relevant](#clinicallyrelevantservice))
The payment of a rebate for a [professional service](#professionalservice) listed in the [MBS](#MBS). Medicare benefits are claimable only for clinically relevant servicesrendered 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](#schedulefee).

**Benefit, net**In a [cost-benefit analysis](#costbenefitanalysis), the total [benefit](#benefit) ([valued](#value) in monetary units) minus the total cost.

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

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

**Benefit, single** [PLAC] (see [benefit, group](#groupbenefit))

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

**Bias** (see [variation, systematic](#systematicvariation))

**Bias, observer**The error due to systematic differences between the true [value](#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](#trial) or [study](#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](#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](#trial)or[study](#study)outcomes ignorant of the [health technology](#healthtechnology) group to which the participants have been allocated. In a [diagnostic accuracy study](#diagnosticaccuracystudy), blinding also involves being ignorant of the participant’s disease status.

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

**Budgetary analysis** (see [analysis, financial](#financialanalysis))

**Budget impact analysis** (see [analysis, financial](#financialanalysis))

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**CAG** [PLAC]
Clinical Advisory Group

**Cardinal data** (see [data, cardinal](#cardinaldata))

**Case-control study** (see [study, case-control](#casecontrolstudy))

**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](#data) about classifications that are clinically meaningful and explain variation in [resource](#resource)use.

**Case series**
A [study](#study) where the use of a [health technology](#healthtechnology) 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](#controlgroup)for comparison.

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

**Catch-up vaccination program** (see [vaccination program, catch-up](#catchupvaccinationprogram))

**Categorical data** (see [data, categorical](#categoricaldata))

**Causality** (see also [association](#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](#outcome) is causal: strength of association; consistency; [specificity](#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](#randomvariation))

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

**Chi-square test**A test based on comparison of a [statistic](#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](#healthtechnology) 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)](#PLAC) that primarily advises PLAC on [applications](#application) to list [prostheses](#prosthesis) and their [clinical effectiveness](#clinicaleffectiveness)on the [Prostheses L](#PL)ist.

**Clinical assessment** [PLAC] (see [assessment, clinical](#clinicalassessment))

**Clinical effectiveness** (see [effectiveness, clinical](#clinicaleffectiveness))

**Clinical heterogeneity** (see [heterogeneity, clinical](#clinicalheterogeneity))

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

**Clinical management algorithm, current**The set of [clinical pathways](#clinicalpathway) that define the stream of [health care resources](#healthcareresource) 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](#healthtechnology) 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](#clinicalpathway) that define the stream of [health care resources](#healthcareresource) that would be provided over time to manage a patient population if the proposed[health technology](#healthtechnology) 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](#healthcareresource) provided over time (including how frequent and when) to an individual under the circumstances defined for the [health technology](#healthtechnology).

**Clinically equivalent** [PLAC]A proposed [prosthesis](#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](#statisticallysignficant))The extent to which a [treatment effect](#treatmenteffect) or other [outcome](#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](#clinicallyrelevantservice))

**CMA**Cost-minimisation analysis

**Co-administered intervention** (see [intervention, co-administered](#coadministeredintervention))

**Cochran *Q* statistic** (see also [*I2* statistic](#I2statistic))A measure of [statistical heterogeneity](#statisticalheterogeneity) in a [meta-analysis](#metaanalysis). It is the sum of the squared deviations of the [estimates](#estimate)of each [trial](#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](#healthtechnology) 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](#healthoutcome) of either health technology.

**Cohort-expected value analysis** (see [analysis, deterministic](#analysisdeterministic))

**Cohort study** (see [study, cohort](#cohortstudy))

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

**Common reference**A [health technology](#healthtechnology) (including placebo or watchful waiting for no health technology) against which the proposedhealth technology and its [main comparator](#maincomparator) have been compared in separate [direct randomised trials](#directrandomisedtrial).

**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](#medicalcondition).

**Comparative cost** (see [cost, comparative](#comparativecost))

**Comparative safety** (see [safety, comparative](#comparativesafety))

**Comparator, main** (see also [indication, main](#mainindication))The existing[health technology](#healthtechnology) (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](#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](#diagnosisrelatedgroup), diagnoses that are likely to result in significantly greater [resource consumption](#consumptionofresource).

**Composite outcome** (see [outcome, composite](#compositeoutcome))

**Condition, medical**The health state of a person that might require [therapy](#therapy).

**Conditional listing** [PLAC]A listing (for selected [prostheses](#prosthesis)) 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](#probability) (by convention, 95%) that the true [value](#value) of a [variable](#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](#healthtechnologytherapeutic)) on the [risk](#Risk) of an [outcome](#outcome) of interest brought about by the [association](#association) of the exposure with one or more other factors that can influence the outcome.

**Conjoint analysis** (see [analysis, conjoint](#conjointanalysis))

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

**Consequence** (see [outcome](#outcome))

**Conservative**Generally, a resistance to change. A behavioural response to [uncertainty](#uncertainty) involving harm, costs and [benefits](#benefit) 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](#Estimate) or [values](#value) 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](#healthoutcome). 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](#medicalcondition).

**Consumption of resources** (see[resources, consumption](#consumptionofresource))

**Contingent valuation (CV)** (see [valuation, contingent](#contingentvaluation))

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

**Continuous data** (see [data, continuous](#continuousdata))

**Contracted assessment** [MSAC] (see [assessment, contracted](#contractedassessment))

**Control group** (see [group, control](#controlgroup))

**Co-payment** [MSAC](see [cost, gap](#gapcost); [cost, out-of-pocket](#outofpocketcost); [gap, patient](#patientgap))

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

**Correlation** (see [association](#association))

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

**Cost, comparative**How much one [health technology](#healthtechnology) costs compared to an alternative health technology.

**Cost, direct**The [value](#value) of all [health care resources](#healthcareresource) that are provided with a [health technology](#healthtechnology)or in dealing with [adverse outcomes](#outcomeadverse), or other current and future consequences linked to the health technology.

**Cost, economic or opportunity**The [value](#value)of the best alternative use of a [resource](#resource) that is foregone as a result of its current use.

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

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

**Cost, health care resource**The monetary [value](#value) of a [resource](#resource) provided to deliver health care services as part of the clinical managementof a [medical condition](#medicalcondition), disease or disorder.

**Cost, incremental**The absolute difference between the costs of alternative [health technologies](#healthtechnology) for the same [medical condition](#medicalcondition), disease or disorder.

**Cost, marginal**The extra cost of producing one extra unit of a [resource](#resource).

**Cost, net**In an [incremental analysis](#incrementalanalysis), the monetary [value](#value) of any increase in [resource provision](#resourceprovision) minus any cost offsets — for example, those resulting from an improvement in [outcome](#outcome).

**Cost, out-of-pocket** (see also [cost, gap](#gapcost))

A cost, in relation to the [Extended Medicare Safety Net](#EMSN), that refers to the difference between the [Medicare Benefit](#Medicarebenefit), including any benefits paid through the [Original Medicare Safety Net](#OMSN) and the [fee charged](#feecharged) by the practitioner for out-of-hospital services.

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

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

**Cost-consequence analysis** (see also [natural unit](#naturalunit); compare with [cost-effectiveness analysis](#costeffectivenessanalysis))An [economic evaluation](#economicevaluation) that compares [health technologies](#healthtechnology) as an array of all material costs and [outcomes](#outcome) 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](#valueformoney))[MSAC](#MSAC) considers a proposed medical service to be cost-effective if it considers that, for a specified [main indication](#mainindication), the [incremental benefits](#incrementalbenefit) of clinical management involving the proposed medical service over clinical management involving its [main comparator(s)](#maincomparator) justify its [incremental costs](#incrementalcost) and harms.

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

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

**Cost-effectiveness acceptability curves**A graph that summarises the results of a [cost-effectiveness analysis](#costeffectivenessanalysis) by plotting a range of possible cost-effectiveness thresholds on the horizontal axis against the [probability](#probability) that the proposed [health technology](#healthtechnology) will be [cost-effective](#costeffective)on the vertical axis.

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

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

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

**Cost neutral**The result of a [financial analysis](#financialanalysis) that concludes that implementing the proposed[health technology](#healthtechnology) would neither increase nor decrease costs to the government.

**Cost-utility analysis (CUA)**An [economic evaluation](#economicevaluation) that compares [health technologies](#healthtechnology) in which costs are measured in monetary terms, and [outcomes](#outcome) are measured in terms of extension of life and the [utility](#utility) [value](#Value) of that extension (such as [quality-adjusted life-years](#QALY) or [healthy-year equivalents](#HYE)).

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

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

**Cross-sectional study** (see [study, cross-sectional](#crosssectionalstudy))

**CUA**Cost-utility analysis

**CV**Contingent valuation

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**DAP**Decision analytic protocol

**Data** (see also [evidence](#evidence); [opinion](#opinion))
Measurements of [variables](#variable) of interest.

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

**Data, categorical**
[Data](#data) in which the [variables](#variable) can only have discrete [values](#value).

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

**Data, dichotomous** (see also [data, continuous](#continuousdata))[Data](#data) that are classified into either one of two mutually exclusive [values](#value) — for example, ‘yes’ and ‘no’, or ‘cured’ and ‘not cured’.

**Data, nominal**[Data](#data) that have been classified into unordered qualitative categories.

**Data, ordinal**[Data](#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](#value) is undefined or unknown), mutually exclusive categories.

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

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

**Data, time-to-event** (see also [data](#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](#decisionanalysis))

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

**Decision tree**A flow diagram depicting the probable consequences of the various decision options in a [decision analysis](#decisionanalysis).

**DerSimonian–Laird random effects model** (see [model, random effects](#randomeffectsmodel))

**Description** [PLAC]The details specific to a [product](#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](#analysisdeterministic))

**Device, included medical** [PLAC]
A [medical device](#devicemedical) 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)](#ARTG), and which has been issued with a unique identification number.

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

1. Any [instrument](#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](#diagnosis), prevention, monitoring, [treatment](#treatment)or alleviation of disease

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

iii. [investigation](#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](#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](#medicalcondition) by [investigation](#investigation).

**Diagnosis, differential**The process of considering the possible causes of a patient’s complaint before making a [diagnosis](#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](#resource) 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](#value), and is given a weight of 1.

**Diagnostic accuracy study** (see [study*,* diagnostic accuracy](#diagnosticaccuracystudy))

**Dichotomous data** (see [data, dichotomous](#dichotomousdata))

**Differential diagnosis** (see [diagnosis, differential](#differentialdiagnosis))

**Direct cost** (see [cost, direct](#directcost))

**Direct description of quality of life** (see [quality of life, direct description of](#directdescriptionofqualityoflife))

**Direct elicitation of utility** (see [utility, direct elicitation of](#directelicitationofutility))

**Direct randomised trial** (see [trial, direct randomised](#directrandomisedtrial))

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

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

**Discount rate** (see [rate, discount](#discountrate))

**Discrete choice experiment** (see also [analysis, conjoint](#conjointanalysis))
A survey method of [data](#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](#value) 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](#dispensedprice))

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

**DoHA**Australian Government Department of Health and Ageing

**Dominance**When clinical management involving one [health technology](#healthtechnology) has greater overall [clinical effectiveness](#clinicaleffectiveness) and lower overall costs than clinical management involving a different health technology, it is said to have dominance.

**Double-blind**A [trial](#trial) or [study](#study) design in which both the participants and observers responsible for measuring the [outcomes](#outcome) are kept ignorant of the group to which participants are assigned.

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

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

**DPMQ**Dispensed price for maximum quantity

**DRG**Diagnosis-related group

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

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

**DUSC**Drug Utilisation Sub-Committee

**DVA**Australian Government Department of Veterans’ Affairs

**Dynamic model** (see [model, dynamic](#dynamicmodel))

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**Economic analysis** (see [analysis, economic](#economicanalysis))

**Economic cost** (see [cost, economic or opportunity](#economicoropportunitycost))

**Economic evaluation**A comparative analysis of the costs and [outcomes](#outcome) of [health technologies](#healthtechnology). An umbrella term covering [cost-benefit analysis](#costbenefitanalysis), [cost-effectiveness analysis](#costeffectivenessanalysis), [cost-consequence analysis](#costconsequenceanalysis), [cost‑minimisation analysis](#costminimisationanalysis)and [cost-utility analysis](#costutilityanalysis). The analysis involves identification, [measurement](#measurement) and [valuation](#valuation) of the differences in costs and outcomes caused by substituting health technologies.

**Economic evaluation, modelled** (see also [economic evaluation, stepped](#steppedeconomicevaluation))
An [economic evaluation](#economicevaluation) based on [inputs](#input) and [outcomes](#outcome) obtained from sources other than, or in addition to, one or more [direct randomised trials](#directrandomisedtrial).

**Economic evaluation, stepped** (see also [economic evaluation, modelled](#modelledeconomicevaluation))
An [economic evaluation](#economicevaluation) that is presented in at least three sequential steps, derived from [inputs](#input) and [outcomes](#outcome) [translated](#translationtranslated) from [direct randomised trials](#directrandomisedtrial) and other sources:

1. The first step is a [trial-based economic evaluation](#trialbasedeconomicevaluation) that is derived from the unmodified [trial](#trial)-based [estimate](#Estimate) of [treatment effect](#treatmenteffect) on the incremental provision of [health care resources](#healthcareresource) and incremental [health outcomes](#healthoutcome). Steps 2 and 3 should be presented if the trial-based economic evaluation is not sufficient to provide the [base case](#basecase).

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](#circumstancesofuse) identified by the requested [restriction](#restriction), using a [modelled economic evaluation](#modelledeconomicevaluation).

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

**Economic evaluation, trial-based**An [economic evaluation](#economicevaluation) based only on [inputs](#input) and [outcomes](#outcome) reported in one or more [direct randomised trials](#directrandomisedtrial).

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

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

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

**Efficiency** (see also [efficiency, allocative](#allocativeefficiency); [efficiency, technical](#technicalefficiency))
The extent to which the maximum possible [benefit](#benefit) is achieved out of the available [resources](#resource).

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

**Efficiency, technical** (see also [efficiency](#efficiency); [efficiency, allocative](#allocativeefficiency))
The production of the greatest amount or quality of [outcomes](#outcome) for any specified level of [resources](#resource).

**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](#fundingarrangement) promote fairness by promoting affordable access to [cost-effective](#costeffective)[health technologies](#healthtechnology).

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

**Error, random** (see [variation, random](#randomvariation) )

**Error, systematic** (see [variation, systematic](#systematicvariation))

**ESC** [MSAC]Evaluation Sub-committee

**ESC** [PBAC]Economics Sub-Committee

**Established service** (see [service, clinically relevant](#clinicallyrelevantservice))

**Estimate**The [value](#value) of a quantity that is known, believed or suspected of incorporating some amount of error.

**Etiologic fraction** (see [risk, attributable](#attributablerisk))

**Evaluation group** [PBAC](see [group, evaluation](#evaluationgroup))

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

**Evidence** (see also [data](#data); [opinion](#opinion))An umbrella term covering [data](#data) and [opinion](#opinion).

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

**Evidence, strength of**The magnitude, [precision](#precision) and [reproducibility](#reproducibility) of the effect of the [health technology](#healthtechnology) (includes magnitude of the effect size, [confidence interval](#confidenceinterval)width, [*P*-value](#pvalue) 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](#association) may be considered.

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

**Exposed group** (see [group, exposed](#exposedgroup))

**Extended Medicare Safety Net (EMSN)** (see [Safety Net, Extended Medicare](#EMSN))

**Extended Medicare Safety Net (EMSN) benefit cap** (see also [Safety Net, Extended Medicare](#EMSN))The EMSN benefit cap is an upper limit on the EMSN benefit that can be paid through the [EMSN](#EMSN) for an [MBS](#MBS) item. The EMSN benefit cap does not limit the [out-of-pocket costs](#outofpocketcost) 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](#schedulefee).

**External validity** (see [validity, external](#externalvalidity))

**Extrapolation/extrapolated** (see also [translation/translated](#translationtranslated))An assessment of the extent to which the [outcomes](#outcome) reported within the [trial](#trial) or [study](#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.

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**False negative rate** (see [rate, false negative](#falsenegativerate))

**False positive rate** (see [rate, false positive](#falsepositiverate))

**Fee, Schedule** (compare with [fee charged](#feecharged); [benefit, Medicare](#Medicarebenefit))A Schedule Fee is determined by the government for each medical service listed in the [MBS](#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](#Medicarebenefit) for a service is calculated from the Schedule Fee.

**Fee charged** (compare with [benefit, Medicare](#Medicarebenefit); [cost, out-of-pocket](#outofpocketcost); [Fee, Schedule](#schedulefee)) The fee charged to the patient by the provider of a [professional service](#professionalservice) listed in the [MBS](#MBS).

**Final outcome** (see [outcome, final](#finaloutcome))

**Financial analysis** (see [analysis, financial](#financialanalysis))

**Financial cost** (see [cost, financial](#financialcost))

**Financial implications** (see [analysis, financial](#financialanalysis))

**First-line treatment** (see [treatment, first-line](#firstlinetreatment))

**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](#fixedeffectmodel))

**Focused analytical plan** (see [analytical plan, focused](#focusedanalyticalplan))

**Follow-up**The observation, during a specified time period, of [trial](#trial) or [study](#study) participants to measure changes in [outcomes](#outcome) of interest.

**Force of infection**The [probability](#probability) per unit of time that a susceptible person acquires infection.

**Forest plot**A graphical display of the results of a [meta-analysis](#metaanalysis)depicting the [point estimates](#pointestimate) and [confidence intervals](#confidenceinterval)for each [trial](#trial) with or without the [statistically](#statistic) 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](#valueformoney) by comparing the results of [incremental cost-effectiveness ratios](#ICER) that report comparable [outcomes](#outcome) in the denominator.

**Friction method** (see [method, friction](#frictionmethod))

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

**Funnel plot**A graphical display of some measure of the [precision](#precision) of a [trial](#trial) plotted against the [treatment effect](#treatmenteffect) 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](#schedulefee) 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](#gapcost); [cost, out-of-pocket](#outofpocketcost))Private health insurers can cover the ‘patient gap’ (that is, the difference between the Medicare rebate and the [Schedule Fee](#schedulefee)) for services attracting benefits at the 75% level that can be covered by private health insurers. The benefits are those paid for [professional services](#professionalservice) rendered to a patient as part of an episode of [hospital treatment](#hospitaltreatment) or for professional services rendered as part of an episode of [hospital-substitute treatment](#hospitalsubstitutetreatment).

**Gap cost** (see [cost, gap](#gapcost))

**Generalisability** (see [applicability](#applicabilityapplied))

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

**Gold standard** (see [standard, gold](#goldstandard))

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

**Greatest Permissible Gap (GPG)** (see [Gap, Greatest Permissible](#greatestpermissiblegap))

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

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

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

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

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

**Group/subgroup** [PLAC][Prostheses](#prosthesis) that have comparable features or functions, and are grouped together on the [Prostheses L](#PL)ist.

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**Hazard ratio** (see [ratio, hazard](#hazardratio))

**Head-to-head randomised trial** (see [trial, direct randomised](#directrandomisedtrial))

**Health care resource**A [resource](#resource) provided as part of the clinical managementof a [medical condition](#medicalcondition), 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](#healthcareresourcecost))

**Health care system viewpoint** (see[viewpoint, health care system](#healthcaresystemviewpoint))

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

**Health outcome** (see [outcome, health](#healthoutcome))

**HealthPACT**Health Policy Advisory Committee on Technology

**Health Policy Advisory Committee on Technology (HealthPACT)** A subcommittee of the [Hospital Principal Committee](#hospitalprincipalcommittee)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](#qualityoflife))
A measure of the extent to which an individual is able to function physically, mentally and socially.

**Health technology** (see also [health technology, therapeutic](#healthtechnologytherapeutic); [health technology, investigative](#healthtechnologyinvestigative))A technology used in a health care system — for example, therapeutic services (such as medicines and procedures), [medical devices](#devicemedical), 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 existinghealth 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](#healthtechnologytherapeutic))A type of [health technology](#healthtechnology) 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](#healthoutcome), this information must result in a change in the clinical management of an intermediate [intervention](#intervention). In this sense, investigative procedures can only indirectly improve health outcomes.

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

**Health technology assessment (HTA)** (see [assessment, health technology](#healthtechnologyassessment))

**Healthy-year equivalent (HYE)** (compare with [life-year, quality-adjusted](#QALY))
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)](#QALY) because not only is it based on an individual’s preference for a specific level of [health status](#healthstatus), 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](#healthtechnology) and measurements of [outcomes](#outcome) across a set of [trials](#trial), or the variation in the [internal validity](#internalvalidity)of those trials. That is, clinical heterogeneity refers to differences in methods across [trials](#trial) being compared, implying that it might not be sensible to combine them in a [meta-analysis](#metaanalysis).

**Heterogeneity, statistical**
The variation in the effect of therapy involving a [therapeutic health technology](#healthtechnologytherapeutic) on an [outcome](#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](#measurement) (such as the [risk difference](#riskdifference) on the absolute or additive scale), but not for others (such as the [relative risk](#Riskrelative) or [odds ratio](#oddsratio) 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](#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](#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)](#AHMAC) that, among other things, advises AHMAC on the appropriateness, likely impact, policy implications, effectiveness and [safety](#safety) of clinical and technical developments, particularly in relation to hospital care.

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

**Hospital treatment** (see [treatment, hospital](#hospitaltreatment))

**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](#healthtechnology) should be considered for listing on the [PBS](#PBS), [MBS](#MBS)and the [Prostheses List](#PL), and what the recommended benefit or subsidy should be. Current HTA advisory committees are [PBAC](#PBAC), [MSAC](#MSAC) and [PLAC](#PLAC).

**Human capital method** (see [method, human capital](#humancapitalmethod))

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

**HYE**Healthy-year equivalent

**Hypothetical cohort** (see [analysis, deterministic](#deterministicanalysis))

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***I2* statistic**A [variable](#variable) used to measure the percentage of the variability in effect [estimates](#Estimate) across [trials](#trial) or [subgroups](#subgroup) that is due to [statistical heterogeneity](#statisticalheterogeneity) rather than sampling error (chance). A naive categorisation of [values](#value) for *I2* would not be appropriate for all circumstances, although adjectives of low, moderate and high have been tentatively assigned to *I2* values of 25%, 50% and 75%, respectively.

**ICER**Incremental cost-effectiveness ratio

**Immunogenicity outcome** (see [outcome, immunogenicity](#immunogenicityoutcome))

**Implicit price deflator**A [parameter](#parameter) used to update a unit cost to account for inflation in [prices](#price) since the unit cost was determined.

**Incidence** (compare with [prevalence](#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](#includedmedicaldevice))

**Incremental analysis** (see [analysis, incremental](#incrementalanalysis))

**Incremental benefit** (see [benefit, incremental](#incrementalbenefit))

**Incremental cost** (see [cost, incremental](#incrementalcost))

**Incremental cost-effectiveness ratio (ICER)** (see [ratio, incremental cost-effectiveness](#ICER))

**Incremental safety** (see [safety, incremental](#incrementalsafety))

**Indication**The [medical condition](#medicalcondition), disease or disorder that is the reason for starting clinical management.

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

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

**Inpatient** (see [patient, admitted](#admittedpatient))

**Input**
A [resource](#resource) provided as part of managing a [medical condition](#medicalcondition), disease or disorder. A [variable](#variable) that is included in an analysis or a model.

**Instrument**A tool used to measure a [variable](#variable), including any defined administrative procedures in its use and scoring instructions in its interpretation.

**Intangible outcome** (see [outcome, intangible](#intangibleoutcome))

**Intention to treat (ITT)**A principle of analysis that includes [data](#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](#trial) or [study](#study). This involves following up participants to contribute data and/or prespecifying procedures to deal with missing data.

**Intermediate outcome** (see [outcome, intermediate](#intermediateoutcome))

**Internal validity** (see [validity, internal](#internalvalidity))

**Interval data** (see [data, cardinal](#cardinaldata))

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

**Intervention, co-administered**An [intervention](#intervention) that is given at the same time as the main intervention of interest.

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

**ITT**Intention to treat

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**JBC**Jurisdictional Blood Committee

**Joint analysis** (see [analysis, joint](#jointanalysis))

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

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**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](#Estimate) 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](#withdrawal)) occurs, and are therefore unequal.

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**League table** (see [frame of reference](#frameofreference))

**Leakage**Using a [health technology](#healthtechnology) beyond its approved funding conditions.

**Length of stay (LOS)**The LOS of a patient is measured in patient days. A [same-day](#samedayadmission) 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](#separation) and deducting total leave days. Total contracted patient days are included in the LOS.

**Life-year**An [outcome](#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](#HYE))
An [outcome](#outcome) [measure](#measurement) calculated by weighting the number of [life-years](#lifeyear) by [utility](#utility)[values](#Value) of the [quality of life](#qualityoflife) experienced during those life-years.

**Likelihood ratio** (see [ratio, likelihood](#likelihoodratio))

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

**LOS**Length of stay

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**Main comparator** (see [comparator, main](#maincomparator))

**Main indication** (see [indication, main](#mainindication))

**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](#PBAC) to recommend [PBS](#PBS) coverage at a [price](#price) justified by the existing [evidence](#evidence), pending submission of more conclusive evidence of [cost-effectiveness](#costeffective)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](#devicemedical) 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](#matching))In relation to [utility analyses](#utilityanalysis), a general term to describe approaches to transform generic or disease-specific [quality-of-life](#qualityoflife) measures into [utility](#utility) weights.

**Marginal analysis** (see [analysis, marginal](#marginalanalysis))

**Marginal benefit** (see [benefit, marginal](#marginalbenefit))

**Marginal cost** (see [cost, marginal](#marginalcost))

**Marginal utility** (see [utility, marginal](#marginalutility))

**Marginal value** (see [value, marginal](#marginalvalue))

**Market share**The extent of use of a [health technology](#healthtechnology) in relation to the overall use of all health technologies for a market defined by one or more [indications](#indication).

**Markov model** (see [model, Markov](#Markovmodel))

**Mask/masking** (see [blind/blinding](#blind))

**Matching** (compare with [mapping](#mapping))In relation to [utility analyses](#utilityanalysis), a general term to describe approaches to align [utility](#utility) weights from one set of respondents to a particular [health status](#healthstatus) or [health outcome](#healthoutcome) 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](#MBSfee))

**MBS item**The description of an existing[health technology](#healthtechnology) or other medical service included in the [MBS](#MBS).

**MBS review**An evidence-based review of one or more existing MBS services with regard to [safety](#safety), effectiveness and cost effectiveness. The review will ensure that MBS services align with contemporary clinical practice, represent [value for money](#valueformoney) and provide [health outcomes](#healthoutcome) 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](#value) in the group and dividing by the number of values in the group.

**Measurement**
The procedure of applying a standard scale to a [variable](#variable) or a set of [values](#value).

**Median**
A measure of central tendency. The exact midpoint of a distribution of [data](#data) that is ordered from the highest to the lowest [value](#value).

**Medical condition** (see [condition, medical](#medicalcondition))

**Medical device** (see [device, medical](#devicemedical))

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

**Medicare, Extended Safety Net** (see [Safety Net, Extended Medicare](#EMSN))

**Medicare, Original Safety Net** (see [Safety Net, Original Medicare](#OMSN))

**Medicare benefit** (see [benefit, Medicare](#Medicarebenefit))

**Medicare Benefits Schedule (MBS)**Under the authority of the *Health Insurance Act 1973*, a listing and description of the [professional services](#professionalservice) for which a [Medicare benefit](#Medicarebenefit) 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](#MBS).

**Meta-analysis** (see also [meta-regression](#metaregression); compare with [systematic overview](#systematicoverview); [systematic review](#systematicreview))A [statistical](#statistic) combination of results from independent randomised [trials](#trial).

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

**Method, friction** (see also [method, human capital](#humancapitalmethod))
A method of estimating the [production change](#productionchange) 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](#frictionmethod))A method of estimating the [production change](#productionchange) associated with illness based on the sum of the remaining lifetime earnings of each healthy individual of particular ages [valued](#value) 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](#clinicallyimportant) when considering overall [benefits](#benefit) and harms to health.

**Model, Cox proportional hazards**A [statistical](#statistic) model in survival analysis asserting that the effect of the [trial](#trial) or [study](#study)factors on the hazard ratein the [studypopulation](#studypopulationandsetting) is multiplicative and does not change over time.

**Model, decision analytic**A model that informs a [decision analysis](#decisionanalysis).

**Model, dynamic** (compare with [model, static](#staticmodel))
A model applied in the context of vaccination, and usually structured as a [decision analytic model](#decisionnanalyticmodel) (such as a [Markov model](#Markovmodel)) in which the [force of infection](#forceofinfection) 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](#randomeffectsmodel))The model used in a [meta-analysis](#metaanalysis)based on the assumption that all [trials](#trial) are estimating the same [treatment effect](#treatmenteffect) and that the difference in effect observed across trials is only due to chance.

**Model, Markov**An iterative [decision analytic model](#decisionnanalyticmodel) that represents the changes in the proportions of individuals who are in different discrete health states based on [probabilities](#probability) 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](#fixedeffectmodel))
The model used in a [meta-analysis](#metaanalysis) based on the assumption that the [treatment effect](#treatmenteffect) truly differs across [trials](#trial) 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](#dynamicmodel))
A model applied in the context of vaccination, and usually structured as a [decision analytic model](#decisionnanalyticmodel) (such as a [Markov model](#Markovmodel)) in which the [force of infection](#forceofinfection) is constant over time.

**Modelled economic evaluation** (see [economic evaluation, modelled](#modelledeconomicevaluation))

**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](#instrument) that has the following three elements:

* a descriptive system comprising a generic [health-related quality-of-life](#healthrelatedQOL) questionnaire containing a set of items or statements with multiple response categories
* a scaling technique used to derive [preference](#preference)-based rankings in a sample of the health states covered by the descriptive system

a scoring algorithm that is used to extrapolate [data](#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](#trial)or[study](#study). The statistical analysis should be adjusted to account for the increasing chance that a result will have a [*P*-value](#pvalue) of less than 0.05.

**Multiple Operation Rule (MOR)** (see [Rule, Multiple Operation](#MOR))

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**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](#costconsequenceanalysis); [cost-effectiveness analysis](#costeffectivenessanalysis))
The unit by which a [health outcome](#healthoutcome) or [health care resource](#healthcareresource) is measured and reported (such as [life‑years](#lifeyear) gained, cases not detected, mmHg for blood pressure, prescription packs for medicines, admissions for hospital care).

**Negative predictive value (NPV)** (see [value, negative predictive](#NPV))

**Net benefit** (see [benefit, net](#netbenefit))

**Net cost** (see [cost, net](#netcost))

**NIP**National Immunisation Program

**NNH**Number needed to harm

**NNT**Number needed to treat

**Nominal data** (see [data, nominal](#nominaldata))

**Nonadmitted patient** (see [patient, nonadmitted](#nonadmittedpatient))

**Nonhealth care resource**A [resource](#resource) required as a result of the [medical condition](#medicalcondition), 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](#equivalence))
The proposed[health technology](#healthtechnology) is no worse (primarily in terms of effectiveness) than its [main comparator](#maincomparator).

**Noninferiority threshold** (see [minimal clinically important difference](#MCID))

**NPPL**National Products Price List

**NPV**Negative predictive value

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

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

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**Observational study** (see [study, observational](#observationalstudy))

**Observer bias** (see [bias, observer](#observerbias))

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

**Odds ratio** (see [ratio, odds](#oddsratio))

**OMSN**
Original Medicare Safety Net

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

**Opportunity cost** (see [cost, economic or opportunity](#economicoropportunitycost))

**Ordinal data** (see [data, ordinal](#ordinaldata))

**Original Medicare Safety Net (OMSN)** (see [Safety Net, Original Medicare](#OMSN))

**Orphan drug**A medicine that is used to treat a rare disease or disorder, and is registered under special arrangements by the [TGA](#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](#provisionofresources) following the start of clinical management.

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

**Outcome, composite**A prespecified [outcome](#outcome) of a [trial](#trial) or [study](#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](#outcome) of clinical management or disease in terms of overall effect on both [quality of life](#qualityoflife) and life expectancy.

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

**Outcome, immunogenicity**A [surrogate outcome](#surrogateoutcome) that measures the effect of a [vaccine](#vaccine) on the immune system of the vaccinated individual.

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

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

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

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

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

**Outcome, surrogate** (see also [outcome, intermediate](#intermediateoutcome))
A [variable](#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](#finaloutcome) (such as intraocular pressure as a surrogate for glaucoma).

**Outmoded** (see [obsolete](#Obsolete))

**Out-of-pocket cost** (see [cost, out-of-pocket](#outofpocketcost))

**Outpatient** (see [nonadmitted patient](#nonadmittedpatient))

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

**Parallel group** (see [group, parallel](#parallelgroup))

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

**PASC**Protocol Advisory Sub-committee

**Pathology Services Table (PST)**Lists the pathology tests for which [Medicare benefits](#Medicarebenefit) are available, their [Schedule Fees](#schedulefee) 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](#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](#nonadmittedpatient))
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](#admittedpatient))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](#PBS) medicine when it is dispensed.

**Patient gap** (see [gap, patient](#patientgap))

**Patient-relevant outcome** (see [outcome, patient-relevant](#patientrelevantoutcome))

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

**PBAC**Pharmaceutical Benefits Advisory Committee

**PBS**Pharmaceutical Benefits Scheme

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

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

**Pharmaceutical benefit** (see [benefit, pharmaceutical](#pharmaceuticalbenefit))

**Pharmaceutical Benefits Advisory Committee (PBAC)**An independent [HTA advisory committee](#HTAadvisorycommittee) of the Australian Government that primarily makes recommendations to the health minister on the listing of medicines in the [PBS](#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](#PMS); [vigilance](#vigilance))Coordinated activities encompassing surveillance to identify and evaluate previously unconfirmed undesirable effects of medicines, and measures taken in response to reduce the [risk](#Risk) of these effects.

**PLAC**Prostheses List Advisory Committee

**PMS**Post-market surveillance

**PoCE**Panel of Clinical Experts

**Point estimate**An [estimate](#Estimate) of the [parameter](#parameter) of interest.

**Positive predictive value (PPV)** (see [value, positive predictive](#PPV))

**Post-market surveillance (PMS)** (see also [vigilance](#vigilance))The activity of monitoring the performance of a [health technology](#healthtechnology) 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](#variance))
A measure of the variability or [random variation](#randomvariation) in a set of [data](#data). The inverse of [variance](#variance).

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

**Premodelling study**An analysis used to provide [inputs](#input) for a [stepped](#steppedeconomicevaluation) or [modelled economic evaluation](#modelledeconomicevaluation), including by [translating](#translationtranslated) [evidence](#evidence) from the clinical evaluation.

**Present value** (see [value, present](#presentvalue))

**Prevalence** (compare with [incidence](#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](#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](#PBS) illustrates why the purchaser may need to be identified, as the following could all apply: [dispensed price](#dispensedprice); list price or price to chemist; price to wholesaler or [ex-manufacturer price](#exmanufacturerprice).

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

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

**Price advantage**The larger requested or listed [price](#price) of a [health technology](#healthtechnology) compared to its [main comparator(s)](#maincomparator)*.*

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

**Primary analysis** (see [analysis, primary](#primaryanalysis))

**Primary outcome** (see [outcome, primary](#primaryoutcome))

**Primary prevention** (see [prevention, primary](#primaryprevention))

**Primary vaccination program** (see [vaccination program, primary](#primaryvaccinationprogram))

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

**Probabilistic sensitivity analysis** (see [analysis, probabilistic sensitivity](#probabilisticsensitivityanalysis))

**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](#value) that a [parameter](#parameter) may have.

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

**Product information**Information approved by the [TGA](#TGA) relating to the safe and effective use of a [therapeutic good](#therapeuticgood), including information regarding the usefulness and limitations of that good.

**Production change**The [value](#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](#professionalservice))

**Prospective data** (see [data, prospective](#prospectivedata))

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

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

**Prostheses List category** (see [group](#group))

**Prosthesis** (see also [device, medical](#devicemedical))
Refer to the Prostheses List Guide, found at [Prostheses List Guide](http://www.health.gov.au/internet/main/publishing.nsf/content/health-privatehealth-prostheseslistforms).

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

**Provision of resources** (see [resources, provision](#provisionofresources) 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](#PBAC) or [MSAC](#MSAC), so that stakeholders (such as doctors, health professionals and patients) are aware of the rationale for specific [health technology assessment](#healthtechnologyassessment) recommendations, and gain an improved understanding of the overall [PBS](#PBS) or [MBS](#MBS) listing process.

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

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**Q-TWiST**Quality-adjusted time without symptoms and toxicity

**QALY**
Quality-adjusted life-year

**Quality-adjusted life-year (QALY)** (see [life-year, quality-adjusted](#QALY))

**Quality-adjusted time without symptoms and toxicity (Q-TWiST)**Developed originally for cancer care, a method of estimating [quality-adjusted life-years](#QALY) that divides life expectancy into time with [toxicity](#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](#utility) weight.

**Quality of evidence** (see [evidence, quality of](#qualityofevidence))

**Quality of life** (see also [health status](#healthstatus))
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](#directelicitationofutility)) A description of the impact of a particular [health status](#healthstatus), or a [health outcome](#healthoutcome) or [quality of life](#qualityoflife) 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](#quasiexperimentalstudy))

**QUM**Quality use of medicines

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**Random effects model** (see [model, random effects](#randomeffectsmodel))

**Random error** (see[variation, random](#randomvariation))

**Random variation** (see [variation, random](#randomvariation)).

**Randomisation**The process by which participants are allocated to one of two or more [health technology](#healthtechnology) groups by chance, to thus minimise [selection bias](#selectionbias). Other than [random variation](#randomvariation), the resulting groups are also likely to be similar to one another at the start of the [trial](#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](#randomisedcrossovertrial))

**Rate, discount**The specified percentage used in a formula to convert future costs and/or benefits into equivalent [present values](#presentvalue).

**Rate, false negative**The complement of test [sensitivity](#sensitivity).

**Rate, false positive**The complement of test [specificity](#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](#outcome) of interest relative to another group.

**Ratio, incremental cost-effectiveness (ICER)**A comparison of two alternative [health technologies](#healthtechnology) calculated by dividing the [incremental costs](#incrementalcost) from substituting the proposed health technology for its[main comparator](#maincomparator) by the incremental [healthoutcomes](#healthoutcome) 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](#sensitivity)/(1 minus [specificity](#specificity)). The likelihood ratio of a negative test result is (1 minus sensitivity)/specificity.

**Ratio, odds** (compare with [risk, relative](#Riskrelative))
The ratio of two odds. Usually, this is the ratio of the odds in favour of exposure (such as to the proposed[health technology](#healthtechnology)) among the people with the disease or [outcome](#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](#outcomeadverse))
An unwanted event reported in the approved [product information](#productinformation), 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](#healthtechnology)); 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](#sensitivity) of the test on the vertical axis against (1 minus [specificity](#specificity)) of the test on the horizontal axis, as the threshold [value](#value) for labelling the test positive is varied.

**Reference standard** (see [standard, reference](#referencestandard))

**Regression analysis** (see [analysis, regression](#regressionanalysis))

**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](#Riskrelative))

**Relative risk reduction** (see [risk reduction, relative](#relativeriskreduction))

**Relative value** [MSAC] (see [value, relative](#relativevalue))

**Relevance (of outcomes)**A measure of whether[trial](#trial)or[study](#study) results assess direct improvements in [healthoutcomes](#healthoutcome), such as [quality of life](#qualityoflife) and survival.

**Reliability**The extent to which the results obtained by a [measurement](#measurement) procedure or [instrument](#instrument) can be replicated under identical conditions.

**Repatriation Pharmaceutical Benefits Scheme (RPBS)**Subsidises medicines for the [treatment](#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](#PBS) medicines.

**Reproducibility** (see [reliability](#reliability))

**Resource**
A factor of production, an [input](#input) or a produced good.

**Resources, consumption of (**compare with[resources, provision](#resourceprovision) 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](#consumptionofresource))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](#consumptionofresource)).

**Responsiveness**
The ability of an [instrument](#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](#restrictedbenefit))

**Restricted time-to-event analysis** (see [analysis, truncated time-to-event](#truncatedtimetoeventanalysis))

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

**Retrospective data** (see [data, retrospective](#retrospectivedata))

**Risk** (see also [risk, absolute](#riskabsolute); [risk, baseline](#baselinerisk)) The [probability](#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](#baselinerisk); compare with [risk, relative](#Riskrelative))
The observed or calculated [risk](#Risk) of an event.

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

**Risk, relative** (compare with [risk, absolute](#riskabsolute); [ratio, odds](#oddsratio);[risk difference](#riskdifference))
Within the same time period, the ratio of the [risk](#Risk) of an [outcome](#Outcome) in the [exposed group](#exposedgroup) (such as to clinical management involving the proposed[health technology](#healthtechnology)) to the risk of the same outcome in the [control group](#controlgroup).

**Risk difference** (compare with ;[risk reduction, relative](#relativeriskreduction))Within a specified time period, the difference of the [risk](#Risk) of an [outcome](#Outcome) in the [exposed group](#Experimentalgroup) (such as those with clinical management involving the proposed[health technology](#healthtechnology)) in a [trial](#trial)or [study](#study), and the risk of the same outcome in the [control group](#controlgroup).

**Risk reduction, relative** (compare with [risk, relative](#Riskrelative); [risk difference](#riskdifference))One minus the [relative risk](#Riskrelative). The relative risk reduction can be calculated only when the proposed[health technology](#healthtechnology) is more effective than its [main comparator](#maincomparator)*.*

**Risk-sharing arrangement (RSA)** [PBAC]An arrangement agreed between the supplier of a [PBS](#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](#sensitivityanalysis))
The extent to which the conclusion of an [economic analysis](#economicanalysis) is likely to remain unchanged, even if [estimates](#Estimate) of key [variables](#variable), 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](#Medicarebenefit) are paid in accordance with a reduction in the [Schedule Fee](#schedulefee) 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](#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](#healthtechnology) exists in Australia to treat patients with the [medical condition](#medicalcondition) meeting the criteria of the requested [restriction](#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](#healthtechnology) provides a worthwhile clinical improvement to qualify as rescue from the medical condition.

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**Safety** (compare with [toxicity](#toxicity))The reverse of toxicity.

**Safety, comparative**The [safety](#safety) of one [health technology](#healthtechnology) compared to an alternativehealth technology.

**Safety, incremental**The absolute difference between the [safety](#safety) profiles of alternate [health technologies](#healthtechnology) for the same [medical condition](#medicalcondition), disease or disorder.

**Safety Net, Extended Medicare (EMSN)** (see also [Safety Net, Original Medicare](#OMSN); [Extended Medicare Safety Net benefit cap](#EMSNbenefitcap))

Once a Medicare-eligible family or single reaches the relevant annual threshold in [out-of-pocket costs](#outofpocketcost) 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](#EMSNbenefitcap)’ 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](#schedulefee). 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](#OMSN) include all Medicare-eligible services where the 85% or 100% benefit is paid.

**Safety Net,** **Original Medicare (OMSN)** (see also [Safety Net, Extended Medicare](#EMSN))

The OMSN provides singles and families with an increase in their [MBS](#MBS) rebate to 100% of the [Schedule Fee](#schedulefee) once [gap costs](#gapcost) 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](#study), based on the [minimal clinically important difference (MCID)](#MCID)*,* [power](#power) and the [risk](#Risk) of a [Type I error](#type1error).

**Scenario analysis** (see [analysis, scenario](#scenarioanalysis))

**Scenario-based valuation** (see [valuation, scenario-based](#scenariobasedvaluation))

**Schedule Fee** (see [Fee, Schedule](#schedulefee))

**SCoH**Standing Council on Health

**Screening**Detection of a disease, abnormality or associated [risk](#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](#secondaryanalysis))

**Secondary outcome** (see [outcome, secondary](#secondaryoutcome))

**Secondary prevention** (see [prevention, secondary](#secondaryprevention))

**Second-line treatment** (see [treatment, second-line](#secondlinetreatment))

**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](#selectionbias))

**Sensitivity** (see also [specificity](#specificity))The proportion of individuals classified as positive by the [gold](#goldstandard)(or[reference](#referencestandard))standard who are correctly identified by the [investigativehealth technology](#healthtechnologyinvestigative) (also called the true positive rate).

**Sensitivity analysis** (see [analysis, sensitivity](#sensitivityanalysis))

**Separation**The process by which an [admitted patient](#admittedpatient) completes an [episode of care](#episodeofcare) 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](#Medicarebenefit) are claimable only for clinically relevant services rendered by an appropriate health practitioner.

**Service, professional**Professional services that attract [Medicare benefits](#Medicarebenefit) include existing[health technologies](#healthtechnology) 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](#Adversereaction))

**Significant** (see [statistically significant](#statisticallysignficant))

**Single-arm study** (see [study, single-arm](#singlearmstudy))

**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](#productinformation) or technical documentation.

**Societal viewpoint** (see [viewpoint, societal](#societalviewpoint))

**Specificity** (see also [sensitivity](#sensitivity))The proportion of individuals classified as negative by the [gold](#goldstandard)(or [reference](#referencestandard))standard who are correctly identified by the [investigativehealth technology](#healthtechnologyinvestigative) (also called the true negative rate).

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

* supplying [products](#product), [prostheses](#prosthesis) or [medical devices](#devicemedical) in Australia
* submitting manufacturer’s evidence of conformity to the [TGA](#TGA)

applying for an entry for the product in the [Australian Register of Therapeutic Goods (ARTG)](#ARTG).

**Standard, gold** (see also [standard, reference](#referencestandard))

 The gold standard is a method, procedure or [measurement](#measurement) that is widely accepted to be the best available.

**Standard, reference** (see also[standard, gold](#goldstandard))An independently applied test that is compared with the proposed diagnostic test to ascertain the [accuracy](#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](#utility) for a particular [health status](#healthstatus) or [health outcome](#healthoutcome) where the respondent is offered a choice between two alternatives. Alternative 1 is clinical management with two possible [outcomes](#outcome): either the respondent returns to full health and lives for a fixed number of additional years ([probability](#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](#statetransitionmodel))

**Static model** (see [model, static](#staticmodel))

**Statistic**A [measurement](#measurement) of a [variable](#variable) of interest that is subject to [random variation](#randomvariation).

**Statistical heterogeneity** (see [heterogeneity, statistical](#statisticalheterogeneity))

**Statistical interaction** (see [heterogeneity, statistical](#statisticalheterogeneity))

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

**Stepped economic evaluation** (see [economic evaluation, stepped](#steppedeconomicevaluation))

**Strength of evidence** (see [evidence, strength of](#strengthofevidence))

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

**Study, before-and-after**
A [quasi-experimental study](#quasiexperimentalstudy) in which participants are observed before and after a [health technology](#healthtechnology) is started.

**Study, case-control**
An [observational study](#observationalstudy) in which the past history of exposure to a suspected [risk](#Risk) factor (such as clinical management involving the proposed[health technology](#healthtechnology)) is compared between cases (who have the [outcome](#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](#observationalstudy) 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)](#outcome) 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](#study)in which [resource provision](#resourceprovision) and/or [health status](#healthstatus) is measured across a defined population at the same time.

**Study, diagnostic accuracy**A [study](#study) that compares the [accuracy](#accuracy) of a proposed[investigativehealth technology](#healthtechnologyinvestigative) with a [gold standard](#goldstandard) test.

**Study, observational**A nonrandomised [study](#study) that observes the characteristics and [outcomes](#outcome) over time of participants who do and do not use a particular [health technology](#healthtechnology). An umbrella term covering [cohort](#cohortstudy) and [case-control studies](#casecontrolstudy).

**Study, quasi-experimental**A nonrandomised [study](#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](#trial). An umbrella term for [before-and-after study](#beforeandafterstudy), [case series with historical controls](#caseserieswithhistoricalcontrols) and a comparison of the results of [single-arm studies](#singlearmstudy).

**Study, single-arm**A group of participants with a specified [indication](#indication) and managed with a specified clinical management (such as involving the proposed[health technology](#healthtechnology)) are systematically observed to measure [outcomes](#outcome) of interest. A [quasi-experimental study](#quasiexperimentalstudy)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)](#maincomparator).

**Study population and setting** (see also [target population and setting](#targetpopulationandsetting))The population and setting used in one or more [studies](#study), used to underpin effectiveness or a [cost-effectiveness analysis](#costeffectivenessanalysis).

**Subgroup**A defined set of individuals in a population group or of participants in a [trial](#trial)or [study](#study),such as subgroups defined by sex or age.

**Subgroup analysis** (see [analysis, subgroup](#subgroupanalysis))

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

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

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

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

**Summary statistic**Quantitative [estimate](#Estimate) of the overall effect of a particular [health technology](#healthtechnology) on a particular [outcome](#outcome) obtained from a [meta-analysis](#metaanalysis) of all available [trials](#trial).

**Supplementary analysis** (see [analysis, supplementary](#supplementaryanalysis))

**Surrogate outcome** (see [outcome, surrogate](#surrogateoutcome))

**Survival data** (see [data, time-to-event](#timetoeventdata))

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

**Systematic error** (see [variation, systematic](#systematicvariation))

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

**Systematic review**Research that summarises the [evidence](#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](#study), and to extract, collate and report their findings. Statistical [meta-analysis](#metaanalysis) may or may not be used.

**Systematic variation** (see [variation, systematic](#systematicvariation))

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**Target population and setting** (see also [study population and setting](#studypopulationandsetting))The intended population and setting of the [health technology](#healthtechnology) 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](#evidence) (Module 4) of the application to the [TGA](#TGA) seeking marketing approval for a proposed medicine.

**TGA delegate’s overview**The [TGA](#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](#ACPM).

**Therapeutic class** (see [class, therapeutic](#therapeuticclass))

**Therapeutic good**
[Health technologies](#healthtechnology) regulated by the [TGA](#TGA), including medicines, [medical devices](#devicemedical), 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](#therapeuticgood) available within Australia.

**Therapy** (see also [intervention](#intervention); compare with [investigation](#investigation))
Clinical management of an individual for the purpose of improving [health outcomes](#healthoutcome) by combating (such as preventing, curing, ameliorating) a [medical condition](#medicalcondition), disease or disorder; all [resources](#resource) 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](#healthtechnology), 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](#timetoeventdata))

**Time trade-off (TTO)**A method of eliciting the [utility](#utility) for a particular [health status](#healthstatus) or [health outcome](#healthoutcome) 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](#sensitivityanalysis). The horizontal axis presents the results of the [economic evaluation](#economicevaluation). The vertical axis presents each [sensitivity analysis](#sensitivityanalysis) ranked from the [variable](#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](#healthtechnology) considering the entire profile of [adverse reactions](#reactionadverse) and [adverse outcomes](#outcomeadverse).

**Trace**A graphical display of a [variable](#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](#translationtranslated))
An assessment of the extent to which the [outcomes](#outcome) reported in a [trial](#trial) relate to and/or predict outcomes of greater patient relevance or outcomes [valued](#value) in [utility](#utility) terms, and thus the extent to which the results of the trial can be transformed to be more relevant to an [economic evaluation](#economicevaluation).

**Transition probability**The [probability](#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](#statetransitionmodel).

**Translation/translated** (see also [analytical plan, focused](#focusedanalyticalplan); [transportability](#transportability))
An umbrella term covering [applicability](#applicabilityapplied), [extrapolation](#extrapolationextrapolated) and [transformation](#transformationtransformed), which together convert the [systematic overview](#systematicoverview) of the results of the [direct randomised trial](#directrandomisedtrial) [evidence](#evidence) to the listing requested, and thus to the framework of a [modelled economic evaluation](#modelledeconomicevaluation).

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

**Treatment** (see [therapy](#therapy))

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

**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](#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](#hospitaltreatment); 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](#treatment) that is excluded from this definition.

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

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

**Treatment effect variation** (see [variation, treatment effect](#treatmenteffectvariation))

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

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

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

**Trial-based economic evaluation** (see [economic evaluation, trial-based](#trialbasedeconomicevaluation))

**Triangulation**The use of multiple sources of [data](#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](#truncatedtimetoeventanalysis))

**TTO**
Time trade-off

**Type I error**
The [risk](#Risk) of a false positive result from a study. In a superiority [trial](#trial), it is the [probability](#probability) of detecting a ‘[statistically significant](#statisticallysignficant) difference’ when its [treatments](#treatment) are actually equally effective.

**Type II error**The [risk](#Risk) of a false negative result from a study. In a superiority [trial](#trial), it is the [probability](#probability) of not detecting a ‘[statistically significant](#statisticallysignficant) difference’ when there is actually a difference of a prespecified magnitude.

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**Uncertainty**Any reduction of confidence in a conclusion. [Statistical](#statistic) uncertainty arises from chance (or [random variation](#randomvariation)), when a [variable](#variable) includes a range of [estimates](#Estimate) within which the true [value](#value) of the variable is likely to be found. Inferential uncertainty arises from [bias](#bias) (or [systematic variation](#systematicvariation)) when there are alternative explanations for a measured difference or arises when [translations](#translationtranslated) are made from an estimate. Clinical uncertainty arises when the proposed[health technology](#healthtechnology) has both clinical advantages and disadvantages compared with its [main comparator(s)](#maincomparator). 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](#data).

**Uncertainty interval**The calculated interval with a specified [probability](#probability) (by convention, 95%) that the true *I2*[statistic](#statistic) is contained within the interval.

**Unrestricted benefit** (see [benefit, unrestricted](#unrestrictedbenefit))

**Upstream** (see also [downstream](#downstream))Occurring before the [health technology](#healthtechnology) is initially provided to an individual.

**Utilisation**The number of uses of a [health technology](#healthtechnology) in a specified time period.

**Utility** (see also [preference](#preference))
The numerical [value](#value) assigned by an individual to a [preference](#preference) for, or a desirability of, a specific level of [health status](#healthstatus) or a specific [health outcome](#healthoutcome). 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](#directdescriptionofqualityoflife))A utility for a particular [health status](#healthstatus) or a [health outcome](#healthoutcome) obtained from a respondent who is experiencing it using a [standard gamble](#standardgamble) or [time trade-off](#timetradeoff) technique.

**Utility, marginal**The extra [utility](#utility) caused by providing one extra unit of a [resource](#resource).

**Utility analysis** (see [analysis, utility](#utilityanalysis))

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**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](#primaryvaccinationprogram).

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

**Vaccine**A suspension of attenuated or killed microorganisms administered for the prevention, amelioration or [treatment](#treatment) of infectious diseases.

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

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

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

**Validity, trial or study** (see also [applicability](#applicabilityapplied); [validity, internal](#internalvalidity); [validity, external](#externalvalidity))
The extent to which an inference drawn from a [trial](#trial) or [study](#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](#outcome) in [utility](#utility) or monetary terms, or of quantifying the cost of a [resource](#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](#value) according to the respondents’ maximum [willingness to pay](#willingnesstopay).

**Valuation, scenario-based**[Valuation](#valuation) of one or more health states, each based on a description presented in a scenario format.

**Value** (see also [preference](#preference))
In economics, a quantitative measure of the desirability of an [outcome](#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](#benefit), or to avoid a defined harm. In science, the magnitude of a [measurement](#measurement).

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

**Value, negative predictive (NPV)** (see also [value, positive predictive](#PPV))The [probability](#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](#NPV))The [probability](#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](#value) today of a future cost or benefit after adjusting for time [preferences](#preference) by [discounting](#discountrate).

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

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

**Variable**Any attribute, phenomenon or event that can have different [values](#value).

**Variance** (compare with [precision](#precision))
A measure of the variability or [random variation](#randomvariation) 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](#variable) as being due to chance. An alternative explanation for an apparent [treatment effect](#treatmenteffect), or for an apparent result of an [investigativehealth technology](#healthtechnologyinvestigative) 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](#treatmenteffect), or for an apparent result of an [investigativehealth technology](#healthtechnologyinvestigative) or medical service.

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

**VAS**
Visual analogue scale

**Viewpoint, health care system**The viewpoint for an [economic evaluation](#economicevaluation)that considers all material incremental changes in the provision of [health care resources](#healthcareresource) and all material incremental changes in [health outcomes](#healthoutcome).

**Viewpoint, societal**The viewpoint for an [economic evaluation](#economicevaluation) that considers all material incremental changes in costs and consequences without considering to whom they accrue.

**Vigilance** (see also [post-market surveillance](#PMS))
Proactive monitoring of the marketplace in which a [health technology](#healthtechnology) 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](#healthoutcome) or ensuring that the proposed[health technology](#healthtechnology) is substituted for its [main comparator](#maincomparator) based on valuing the resulting difference(s) in outcomes.

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

**Within-trial analysis** (see [economic evaluation, trial-based](#trialbasedeconomicevaluation))

**WTP**Willingness to pay

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