



Health Technology Assessment Policy and Methods Review: Glossary

When used in documents related to the Health Technology Assessment Policy and Methods Review (HTA Review) words and phrases are to be interpreted as follows (unless otherwise specified). These terms may be updated as the review progresses. If any further questions about the meaning of certain terms please contact htareviewconsult@health.gov.au.

Term	Definition
Australia's National Medicines Policy (NMP) 2022	A high-level framework focused on the availability and the use of medicines and medicines-related services. The NMP relates to medicines research and development, manufacture, regulation, evaluation, supply, dispensing, storage and access. It promotes the quality use of medicines and medicines safety by focusing on the current and future health needs of people and the responsibilities of all partners to achieve the best health, social and economic outcomes for all Australians.
Cabinet	The Cabinet is the council of senior ministers who are empowered by the Australian Government to take binding decision on its behalf.
Cell therapy	The transfer of cells into a patient with the goal of treating a disease. The cells may be from the patient or from a donor. Cell therapies include gene modified cell therapy, which involves removing cells from a patient's body, in order to introduce a new gene or correct a faulty gene in vitro. The modified cells are then put back into the body.
Consumer (health)	A person who uses (or may use) a health service, or someone who provides support for a person using a health service. Consumers can be patients, carers, family members or other support people.
Consumer Consultative Committee (CCC)	The Consumer Consultative Committee is a committee that provides strategic advice and support to the principal Commonwealth HTA advisory committees. It brings consumer views into HTA processes and relevant matters.
Consumer Evidence and Engagement Unit (CEEU)	A unit that was set up in 2019 to develop structured engagement projects with consumer and patient groups. The unit creates opportunities for consumers and patients to contribute to HTA decision making processes. In addition, the CEEU is also the secretariat for the CCC.



Conversations for Change	A series of consultations being held by the CEEU. The consultations considered how to improve the way the Department communicates and engages with and included consumers and carers in HTA.
Cost-effectiveness analysis (CEA)	An economic evaluation that compares health technologies that have a common health outcome in which costs are measured in monetary terms and the outcome is measured in natural units.
Cost-minimisation analysis (CMA)	An economic evaluation that identifies the least costly health technology after the proposed health technology has been demonstrated to be no worse than its main comparator(s) in terms of effectiveness and toxicity.
Cost-utility analysis (CUA)	An economic evaluation that compares health technologies in which costs are measured in monetary terms, and outcomes are measured in terms of extension of life and the utility value of that extension (such as quality-adjusted life-years or healthy-year equivalents).
Effectiveness, clinical	The extent to which a health technology produces its intended outcome(s) in a defined population in uncontrolled or routine circumstances.
Enhanced Consumer Engagement Process	A commitment in the Strategic Agreement between the Commonwealth and Medicines Australia, that the Commonwealth would work with Medicines Australia and consumer, clinician and other stakeholder groups to co-design and agree upon an Enhanced Consumer Engagement Process to capture consumer voices in respect of applications to list new medicines on the Pharmaceutical Benefits Scheme. This co-designed process could reduce the likelihood of multiple reimbursement submissions by assisting the Pharmaceutical Benefits Advisory Committee and other independent HTA advisory bodies, at an early stage, to obtain an understanding of issues arising from new technologies, innovations, and associated implications for consumers.
Equity	The principles of fairness informing decision making
Evaluation (for HTA committees)	Refers to the process undertaken to assess the clinical, economic, financial, and use aspects of health technologies.
First in class technology	<p>A first in class medicine or vaccine, and/or a medicine or vaccine for a new population.</p> <ul style="list-style-type: none"> • A first-in-class medicine or vaccine represents a drug or vaccine with a unique mechanism of action that has not been considered by the PBAC. • A new population could include a disease or medical condition not previously considered by the PBAC.



	<ul style="list-style-type: none">• A disease is intended to cover whole diseases when all stages and genetic subtypes are considered.
Gene therapy	A therapy that uses a gene or genes to treat, prevent or cure a disease or medical disorder. Often, gene therapy works by adding new copies of a gene that is defective, or by replacing a defective or missing gene in a patient's cells with a healthy version of that gene.
Health technology	Health technology refers to health products and services, such as pharmaceuticals (including vaccines), highly specialised therapies, diagnostic tests, medical devices, surgically implanted prostheses, medical procedures, digital health technologies and public health interventions.
Health Technology Assessment (HTA)	Health Technology Assessment (HTA) involves a range of processes and mechanisms that use scientific evidence to assess the quality, safety, efficacy, effectiveness, and cost effectiveness of health services. The purpose of HTA is to provide policymakers, funders, health professionals and health consumers with the necessary information to understand the benefits and comparative value of health technologies and procedures. This information is then used to inform policy, funding, and clinical decisions, and assist with consumer decision-making.
Highly Specialised Therapies (HST)	<p>A category of therapies created under the National Health Reform Agreement Addendum (NHRA) regarding their HTA and funding.</p> <p>Therapeutic Goods Administration (TGA) approved medicines and biologicals delivered in public hospitals where the therapy and its conditions of use are recommended by Medical Services Advisory Committee or PBAC; and the average annual treatment cost at the commencement of funding exceeds \$200,000 per patient (including ancillary services) as determined by the MSAC or PBAC with input from the Independent Hospital Pricing Authority; and where the therapy is not otherwise funded through a Commonwealth program or the costs of the therapy would be appropriately funded through a component of an existing pricing classification.</p> <p>For the purpose of the HTA Review, HST is intended to refer to cell and gene therapies irrespective of the arrangement where those therapies are ultimately funded.</p>
Incremental cost-effectiveness ratios (ICER)	A comparison of two alternative health technologies calculated by dividing the incremental costs from substituting the proposed health technology for its main comparator by the incremental health outcomes from this substitution.



Life Saving Drugs Program (LSDP)	A Commonwealth program that provides fully subsidised access to expensive essential medicines for eligible patients with ultra-rare and life-threatening diseases.
Life Saving Drugs Program Expert Panel (LSDPEP)	The expert panel that considers applications to list new medicines on the LSDP
Lifecycle of a medicine	Refers to the time period from the development of a medicine, through to being made available to consumers, to termination of market supply.
Medical Services Advisory Committee (MSAC)	The Medical Services Advisory Committee (MSAC) is an independent, expert non-statutory committee that appraises medical services/technologies proposed for public funding and provides advice to Government on whether a medical service/technology should be publicly funded. Amendments and reviews of existing services funded on the Medicare Benefits Schedule (MBS) or through other programs
Medicare Benefits Schedule (MBS)	The Medicare Benefits Schedule (MBS) is a list of health professional services that the Australian Government subsidises. MBS items provide patient benefits for a wide range of health services including consultations, diagnostic tests, and operations.
National Health Reform Agreement 2020-25 (NHRA)	An agreement between the Australian Government and all state and territory governments that commits to improving health outcomes for Australians, by providing better coordinated and joined up care in the community and ensuring the future sustainability of Australia's health system. It is the key mechanism for the transparency, governance, and financing of Australia's public hospital system. Through this agreement, the Australian Government contributes funds to the states and territories for public hospital services. This includes services delivered through emergency departments, hospitals, and community health settings.
National Immunisation Program (NIP)	A Commonwealth funding program that provides free vaccines to eligible people to help reduce diseases that can be prevented by vaccination. The immunisations range from birth through to adulthood. The program provides free essential vaccines to protect eligible people against a range of diseases.
Patient	An individual awaiting or under medical care and treatment.
Patient relevant outcomes	An umbrella term covering any health outcome that is perceptible to the patient (the more meaningful to the patient, the greater the patient relevance); any resource provided as part of ongoing clinical



	management of the patient’s medical condition, disease, or disorder; any working time changes; or any intangible outcome. Common examples of patient-relevant outcomes include primary outcomes, quality-of-life or utility measures, and economic outcomes.
PBAC Submission	The submission that a sponsor/pharmaceutical company must make for the PBAC to consider listing of a medicine on the PBS.
Person-centred approach	Refers to an approach that treats each person respectfully as an individual human being, and not just as a condition to be treated. It involves seeking out and understanding what is important to the patient, their families, carers, and support people, fostering trust and establishing mutual respect. It also means working together to share decisions and plan care.
Pharmaceutical Benefits Advisory Committee (PBAC)	The independent, expert advisory committee provided for under the <i>National Health Act 1953</i> . Its primary function is to recommend new medicines for listing on the PBS and vaccines for listing on the National Immunisation Program (NIP). The PBAC is appointed by the Australian Government.
Pharmaceutical Benefits Scheme (PBS)	An Australian Government Program which provides Australians subsidised access to a wide range of medicines for most medical conditions.
Post market assessment/review	A review that is undertaken at a certain time period after a health technology is subsidised. Post-market reviews may be initiated at any time, but the main drivers for a review are recommendations by the PBAC or issues identified through the routine monitoring. Routine monitoring occurs at 24 months post-listing for new major listings, and changes to existing listings of medicines on the PBS. It is important for the Government to continue to monitor clinical and cost-effectiveness of medicines after they have been listed on the PBS. Reviews of cost-effectiveness ensure that the cost of medicines to the PBS appropriately reflects the health outcomes expected and subsequently produced. These reviews are to ensure the quality use of PBS listed medicines and the ongoing sustainability of the PBS.
Quality use of medicines (QUM)	A policy objective that seeks to ensure that medicines are used only when needed, choosing suitable medicines and using medicines safely.
Randomised controlled trial (RCT)	An experiment in which investigators randomly allocate eligible people into intervention groups to receive or not to receive one or more



	interventions that are being compared. The results are assessed by comparing outcomes in the treatment and control groups.
Rare disease	A disease that affects less than five in 10,000 people.
Safety	The inverse of toxicity (harm to health caused by a health technology considering the entire profile of adverse reactions and adverse outcomes). Comparative safety is the safety of one health technology compared to an alternative health technology. Incremental safety is the absolute difference between the safety profiles of alternate health technologies for the same medical condition, disease, or disorder.
Standing Committee on Health, Aged Care and Sport (Standing Committee)	A parliamentary committee that investigates specific matters of policy or government administration or performance in the areas of Health, Aged Care and Sport.
Strategic Agreement	An agreement between the Commonwealth and Medicines Australia. The current Strategic Agreement runs from 2022 to 2027. The Strategic Agreement contains a comprehensive package of reforms to ensure that Australians continue to gain access to break-through new medicines as early as possible. The HTA Review is one of the commitments under the Strategic Agreement.
The Inquiry	The House of Representatives Standing Committee on Health, Aged Care and Sport inquiry into the approval processes for new drugs and novel medical technologies in Australia. The Inquiry commenced, following a referral on 14 August 2020 from the then Minister for Health. The Inquiry is sometimes referred to as the Zimmerman Inquiry.
Therapeutic Goods Administration (TGA)	The part of the Australian Government Department of Health and Aged Care that regulates the quality, safety, and efficacy of therapeutic goods available within Australia.
Ultra-rare disease	A disease that affects 1 or fewer people in 50,000
Uncertainty	<p>Any reduction of confidence in a conclusion. Statistical uncertainty arises from chance (or random variation), when a variable includes a range of estimates within which the true value of the variable is likely to be found.</p> <p>Clinical uncertainty arises when the proposed health technology has both clinical advantages and disadvantages compared with its main comparator(s). Uncertainty also arises when assumptions need to be made in the absence of relevant data.</p>



Unmet clinical need	A condition for which there exists no satisfactory method of diagnosis, prevention, or treatment.
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