

Health Technology Assessment Policy and Methods Review

**Research and analysis plan: evidence to inform the HTA Review**

Consultation 2 (C2)

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Timeline

*\*Note: Dates are indicative only. More information including exact dates will be released as the Review progresses.*

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| **Papers (and relevant lead)** |
| Consumer engagement and consideration in HTA  (Department of Health and Aged Care) |
| Emerging health technologies  (Department of Health and Aged Care) |
| Australian market approval, funding and assessment pathways and timelines and special pathways and equity considerations  (Department of Health and Aged Care) |
| International health technology market approval, funding and assessment pathways  (Adelaide Health Technology Assessment) |
| Early identification of emerging technologies and early value assessment  (Adelaide Health Technology Assessment) |
| HTA Methods: Determination of Population Intervention Comparator Outcome (PICO)  (Adelaide Health Technology Assessment) |
| HTA Methods: Clinical Evaluation  (Adelaide Health Technology Assessment) |
| HTA Methods: Economic Evaluation  (Centre for Health Economics Research and Evaluation) |
| Funding and purchasing decisions and Managing Uncertainty  (Centre for Health Economics Research and Evaluation) |
| Options for optimising the availability and use of real world data and production of real world evidence to support HTA decision-making throughout the lifecycle of health technologies  (Centre of Research Excellence in Medicines Intelligence) |

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| **Terms of Reference: Funding and approval** |
| approaches that incentivise launch of first in class technologies or first major extension of indication |
| equitable distribution and efficient use of limited HTA resources |
| implications of any recommendations for assessment of other health technologies and hospital funding​ |
| management of future advances in health care |
| consideration of equity of access in HTA decision making |
| the feasibility of international work sharing for evaluation of technologies in scope for the HTA Review​ |
| purchasing practices used by comparable international jurisdictions. ​ |

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| Terms of Reference: Policies and methods |
| identification of place of a technology in care and selection of comparators |
| identification of patient relevant outcomes; augmentation of primary clinical evidence with data designed to capture the value of health technologies from the perspective of patients and their communities; incorporation and use of direct input from patients, clinicians and other stakeholders with professional or lived expertise, into HTA evaluations and deliberations |
| evaluations (including how the value of medicines is captured) |
| approaches to increasing transparency in HTA decision-making and communication |
| new technologies, or expanded indications, that provide a substantial improvement in health outcomes compared to relevant alternative therapies and those that do not |
| managing clinical, economic, financial, and other uncertainty throughout the lifecycle of a technology |
| assessment of technologies (such as those for rare and ultra-rare diseases) that would be used for conditions where there is high unmet clinical need that have clinical and economic uncertainty |

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| **Terms of Reference: Health technologies** |
| all medicines and vaccines |
| highly specialised therapies (such as cell and gene therapies) |
| other health technologies that improve health outcomes associated with the technologies above |
| foreseeable changes in health care that may influence, the need, accessibility, effectiveness or cost-effectiveness of new health technologies |

Publication of ‘publication draft’ papers (to facilitate consultation)

RC consider ‘initial draft’ papers and provide feedback to inform ‘publication draft’ papers

RC agree to research protocol

HTA Review consultation 2

Final reports completed

Develop research protocol

Preparation of ‘initial draft’ and ‘publication draft’ papers

In addition to feedback from stakeholders collected through consultations, the HTA Policy and Methods Review will be informed by papers analysing policy and methods used by the Pharmaceutical Benefits Advisory Committee, contemporary research, relevant methodologies and purchasing practices used by comparable international jurisdictions.

These papers will be prepared by the Department of Health and Aged Care and HTA experts. They will consider approaches to HTA in Australia and internationally in depth, from early identification of emerging technologies to ongoing assessment of health technologies after they are subsidised covering the health technologies, policies, methods, funding and approval pathways identified in the terms of reference.