SA Health

Policy

Health Technology Assessment

Version 2.0

Approval date: 31 October 2024

PDS Reference No: D0378

Government
of South Australia

SA Health

1. Name of Policy

Health Technology Assessment

2. Policy statement

This Policy sets out the mandatory requirements that apply across SA Health in relation to Health Technology Assessment (HTA) and the requirement to refer all high-risk and/or high-cost health technologies, as well as those with statewide implications, to the South Australian Policy Advisory Committee on Technology (SAPACT), to enable quality healthcare through the use of innovative health technologies in South Australia that are safe, clinically-effective and/or cost-efficient.

3. Applicability

This policy applies to all employees and contracted staff of SA Health; that is all employees and contracted staff of the Department for Health and Wellbeing (DHW), Local Health Networks (LHNs) including state-wide services aligned with those Networks and SA Ambulance Service (SAAS).

This policy applies in relation to new and emerging health technologies registered on the Therapeutic Goods Administration Australian Register of Therapeutic Goods (TGA ARTG), comprising of diagnostic and treatment interventions such as diagnostic tests, prostheses, implantable devices, and medical and surgical procedures.

Out of scope

Out of scope health technologies include those undergoing clinical, research or ethical trials, as well as those already assessed through other pathways within SA Health such as high-cost medicines, highly specialised therapies, biomedical engineering, pathology, radiology, and blood and tissue products. High-volume, low-cost health technologies are exempt from SAPACT assessment and are currently encompassed in other procurement and assessment processes.

4. Policy principles

SA Health's approach to HTA is underpinned by the following principles:

- > We will support for clinical innovations and health technologies that are proven to be safe, clinically effective and/or cost-effective, to improve patient and health system outcomes.

- > We will maintain a statewide HTA governance framework and associated processes for transparent, timely and effective health technologies evaluation.

- > We will incorporate internationally recognised HTA principles, methodologies and methods to inform evidence-based decision-making.

- > We will promote equity of access to health technologies for all South Australians living in both metropolitan and regional areas.

- > We will support processes to monitor and evaluate patient and clinical outcomes from the implementation of a health technology.

- > We will encourage the building of HTA capacity in SA Health.

5. Policy requirements

Statewide HTA Governance Framework

The SA Health DHW HTA Program must maintain a statewide HTA governance framework to manage and assess the entry of new and emerging health technologies. The HTA framework incorporates delegation of HTA decision-making to the appropriate statewide level and LHN level.

> **Statewide level**: New and emerging health technologies meeting the SAPACT criteria of high-risk, high-cost or those with statewide service planning implications, must be referred for evaluation to SAPACT and obtain a positive or conditional SAPACT Advisory Recommendation, prior to purchase and implementation in SA Health.

> **LHN level:** New and emerging health technologies outside the scope of SAPACT must be subjected to review by the relevant LHN New Technology Committee(s) or a LHN delegate (e.g. LHN Representative(s) to SAPACT), prior to purchase and implementation in the relevant LHNs:

  o CALHN New Clinical Procedures, Services or Other Interventions Committee

  o SALHN New Health Technology & Clinical Practice Innovation Committee

  o NALHN Procedures and Services Committee

  o WCHN New Health Technologies and Interventions Committee

  o Regional LHNs: LHN regional representatives to SAPACT or as delegated.

> The introduction of new and emerging health technologies must also include considerations on the disinvestment of old or obsolete health technologies, to accommodate evolving clinical practice and health service provision.

Statewide HTA review process

> DHW, LHNs, SAAS and statewide clinical networks must comply with Appendix 1. HTA Process Flowchart for the Assessment of New Technologies in SA Health Mandatory Instruction.

> SA Health clinicians and/or clinical groups seeking to use a new health technology must submit the SAPACT Application Form for New Heath Technology to SAPACT, through the relevant LHN New Technology Committee or LHN Representative.

> When the HTA review is completed, the SAPACT Advisory Recommendation must be communicated to the chief applicant of the new health technology and associated Chair(s) of the LHN Health Technology Committee(s).

Engagement and implementation

> LHNs must assist SAPACT in engaging with their LHN clinicians for HTA evaluation and communicate SAPACT Advisory Recommendations and other relevant statewide HTA activities to appropriate LHN stakeholders.

> LHNs must abide by the requirements and implementation of the SAPACT Advisory Recommendations and/or SAPACT HTA Decision Summaries, in line with the LHN's local organisational feasibility, credentialing, scope of practice, competency and financial considerations.

Funding

> Funding decisions of health technology must be managed locally by the LHNs or health services.

Monitoring and reporting of outcomes

> The chief applicant and associated LHN(s) must have processes in place to support the monitoring of newly implemented health technologies and the collection of relevant service, clinical and patient-related outcome data.

> The chief applicant and associated LHN(s) must report adverse outcomes or incidents involving health technologies in accordance with the Clinical Incident Management Policy.

6. Mandatory related documents

The following documents must be complied with under this policy, to the extent that they are relevant:

> Clinical Incident Management Policy

> SAPACT Application Form for New Heath Technology

7. Supporting information

> SAPACT HTA Decision-making Criteria.

> SAPACT Terms of Reference

8. Definitions

> **Chief applicant:** Refers to the lead clinician who submits the SAPACT application form for new health technology.

> **Health technology assessment (HTA):** Refers to the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the clinical, safety cost, economic social, organisational, and ethical issues of a health intervention or health technology (definition provided by the World Health Organisation).

> **Health technologies:** For the purpose of this policy, health technologies are registered on the Therapeutic Goods Administration Australian Register of Therapeutic Goods (TGA ARTG), comprising of diagnostic and treatment interventions such as diagnostic tests, prostheses, implantable devices, and medical and surgical procedures.

> Out-of-scope health technologies include those undergoing clinical, research or ethical trials, as well as those already assessed through other pathways within SA Health such as high-cost medicines, highly specialised therapies, biomedical engineering, pathology, radiology, and blood and tissue products. High-volume, low-cost health technologies are generally exempt from SAPACT assessment and are currently encompassed in other procurement and assessment processes.

> **High-cost health technology:** Health technology in which the predicted expenditure is (a) ≥$100,000 for a LHN per year or (b) ≥$300,000 within the South Australian Public Health System per year.

> **High-risk health technology:** Health technology in which TGA classifies as a class III high-risk medical device, regardless of anticipated expenditure associated with use.

> **New and emerging health technology:** Health technology that demonstrates a certain degree of novelty and innovation, going beyond a simple iteration or upgrade in form and/or function from its predecessor (if one exists). The technology may be entirely new to SA Health or starting to gain some traction for use in one or more LHNs. Additionally, existing health technologies applied to new or expanded clinical indications may also be classified as new and emerging health technologies.

> **SAPACT:** SAPACT is the statewide multi-disciplinary expert advisory committee of the South Australian Department for Health and Wellbeing, providing statewide governance, policy advice and evidence-based evaluation regarding the safety, clinically- and cost-effective use of new and emerging health technologies across SA Health.

> **Statewide service planning implications:** Health technology in which its use and implementation will potentially involve two or more LHNs across SA Health.

> **Statewide services:** means Statewide Clinical Support Services, Prison Health, SA Dental Service, BreastScreen SA and any other state-wide services that fall under the governance of the Local Health Networks.

9. Compliance

This policy is binding on those to whom it applies or relates. Implementation at a local level may be subject to audit/assessment. The Domain Custodian must work towards the establishment of systems which demonstrate compliance with this policy, in accordance with the requirements of the Risk Management, Integrated Compliance and Internal Audit Policy.

Any instance of non-compliance with this policy must be reported to the Domain Custodian for the Clinical Governance, Safety and Quality Policy Domain and the Domain Custodian for the Risk, Compliance and Audit Policy Domain.

10. Document ownership

Policy owner: Domain Custodian for the Clinical Governance, Safety & Quality Policy Domain

Title: Health Technology Assessment Policy

Objective reference number: A6150416

Review date: 31/10/2029

Contact for enquiries: mailto:Health.SAPACT@sa.gov.au

11. Document history

Version	Date approved	Approved by	Amendment notes
1.0	23/04/2015	Portfolio Executive, SA Health	Original policy
2.0	31/10/2024	Deputy Chief Executive, Commissioning and Performance	Update to new policy template under the Policy Framework

12. Appendix

1. HTA Process Flowchart for the Assessment of New Technologies in SA Health Mandatory Instruction

Appendix 1: HTA Process Flowchart for the assessment of New Technologies in SA Health Mandatory Instruction

The following Instruction must be complied with to meet the requirements of this policy.

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┌─────────────────────────────────────┐
│   Application from Chief Applicant   │
│   Clinicians or clinical groups      │
└─────────────────────────────────────┘
                  ↓
┌─────────────────────────────────────┐
│ Endorsed by Head of Department/Unit  │
└─────────────────────────────────────┘
                  ↓
┌─────────────────────────────────────┐
│  Received by LHN New Technology      │
│            Committee                 │
└─────────────────────────────────────┘
                  ↓
┌─────────────────────────────────────┐        ┌──────────────────────────────────────┐
│ TGA class III high-risk, high-cost   │  No    │ Evaluation under LHN Processes        │
│   or statewide implications          │ ────→  │                                       │
└─────────────────────────────────────┘        │ Note: Technologies not registered on  │
                  ↓ Yes                         │ the TGA ARTG may be considered under: │
┌─────────────────────────────────────┐        │ • TGA Special Access Scheme; or       │
│ South Australian Policy Advisory     │ ←──→   │ • TGA Authorised Prescriber Scheme; or│
│ Committee on Technology (SAPACT)     │        │ • Research setting i.e. HREC          │
└─────────────────────────────────────┘        │   Clinical Trial                      │
                  ↓                             └──────────────────────────────────────┘
┌─────────────────────────────────────┐
│  SAPACT Advisory Recommendations     │
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South Australian Policy Advisory Committee on Technology (SAPACT) ↔ **SAPACT Application Review**

- Undertake health technology assessment review
- Assess local pricing, utilisation and economics analysis
- Organise local clinical consultations
- Check national/interstate utilisation and funding activities
- Ascertain industry information, including device safety information as relevant
- Correspondence with Chief Applicant and LHN New Technology Committee(s)
- Chief Applicant attends SAPACT meeting
- Evaluation by SAPACT Lead Reviewers
- Develop and endorse SAPACT Advisory Recommendations
- Publish SAPACT HTA Decision Summary on SAPACT webpage
- Mutual sharing of reporting schedules and reports received with relevant LHNs to reduce duplicate reporting

Recommended

Recommended for clinical use with no further need for assessment

Restricted recommendation for clinical use subjected to implementation under audit conditions.

Restricted recommendation for clinical use with financial or operational restrictions.

Not recommended

Not recommended for clinical adoption at this time. Re-application may be undertaken in the future.

Not recommended subject to implementation in clinical trial with approval from SA Health HREC

As required, noted or endorsed by **SA Health Chief Executive Council**

LHNs consider clinical governance, implementation and funding