

# Health Technology Assessment (HTA) Decision-Making Criteria

SAPACT MEETING DATE	<X> SAPACT Meeting <DD Month YYYY>
APPLICATION #	
NAME OF TECHNOLOGY	
PATIENT INDICATION	<Inclusion/exclusion criteria appropriate/ not appropriate; Adult/children; Age group>
REGULATORY APPROVALS	<Have regulatory approvals been met? ARTG; US FDA; EU CE mark>

QUALITY OF EVIDENCE		REMARKS
<b>Methodological Quality</b>	<ul style="list-style-type: none"> <li>&gt; Is the quality of evidence appraised for individual studies using critical appraisal checklists for systematic reviews, RCTs, observational and descriptive studies?</li> <li>&gt; Have studies with poor methodological quality been excluded in the systematic review/HTA in order to produce a better estimate of treatment effect?</li> </ul>	
<b>Hierarchy of Study Designs</b>	<ul style="list-style-type: none"> <li>&gt; Levels of evidence are based on how study designs limit the risk of bias</li> <li>&gt; Each type of evidence is assigned a level of evidence to provide an estimate of credibility of the review findings</li> </ul>	
<b>Grades of Recommendation</b>	<p>Consider:</p> <ul style="list-style-type: none"> <li>&gt; Whether the desirable effects outweigh undesirable effects</li> <li>&gt; Whether there is evidence of adequate quality supporting its use</li> <li>&gt; Whether there is a benefit or no impact on resource use, and</li> <li>&gt; Whether values, preferences and the patient experience were taken into account.</li> </ul>	
CLINICAL NEED		
<b>Burden of Illness</b>	<p>The burden of illness on society of the target condition to which the technology is applied</p> <p>(e.g. incidence, prevalence, years of life lost, years live with disability, disability adjusted life years).</p>	
<b>Need</b>	<p>The need for the technology compared to the availability of alternatives to manage the target condition.</p>	
CLINICAL BENEFIT		
<b>Safety</b>	<p>Frequency and severity of adverse events specific to the technology, including comparing with available alternatives.</p>	
<b>Effectiveness</b>	<ul style="list-style-type: none"> <li>&gt; Effectiveness of the technology, including comparing with available alternatives.</li> <li>&gt; May be measured in terms of relative risk, odds ratios, mortality, survival, morbidity, length of stay, etc.</li> <li>&gt; The magnitude and direction of the technology's effect should be considered.</li> </ul>	
<b>Suitability of Patient Selection</b>	<p>Is the proposed patient selection group appropriate?</p>	
FINANCIAL CONSIDERATION		
<b>Cost of health technology</b>	<ul style="list-style-type: none"> <li>&gt; Cost of system/device inclusive of GST; any discount</li> <li>&gt; Total projected cost of device for local health network</li> <li>&gt; No. of patients proposed per annum</li> </ul>	

<b>Affordability / Economic Feasibility</b>	<ul style="list-style-type: none"> <li>&gt; <i>The net budget impact of the new technology.</i> <ul style="list-style-type: none"> <li>– <i>Cost of work-up</i></li> <li>– <i>Cost of hospitalisation</i></li> <li>– <i>Costs for other system enablers (e.g. IT, capital works, workforce remuneration/ recruitment/ training)</i></li> <li>– <i>Downstream costs</i></li> </ul> </li> <li>&gt; <i>Funding implications (Statewide/ Superspecialty status, etc)</i></li> </ul>	
<b>Value for Money</b>	<ul style="list-style-type: none"> <li>&gt; <i>Cost-effectiveness analysis: Compares the relative costs and health outcomes (effects) of a technology.</i></li> <li>&gt; <i>Cost-utility analysis: Cost per Quality-adjusted life-years (QALYs) or incremental cost-effectiveness ratio (ICER)</i></li> <li>&gt; <i>A measure of the net cost or efficiency of the technology compared to available alternatives. Experience from international/ other jurisdictions can be used.</i></li> </ul>	
<b>Australian Funding Approvals</b>	> <i>Whether the health technology received MSAC/HealthPACT's approval</i>	

**FEASIBILITY OF ADOPTION** (relevant when safety, clinical and cost-effectiveness are met)

<b>Organizational Feasibility</b>	<ul style="list-style-type: none"> <li>&gt; <i>The ease with which the health technology can be adopted by looking at other enablers and/or barriers to diffusion</i></li> <li>&gt; <i>Infrastructure/geography/clinical services capability framework/impact on other service streams (e.g. rehabilitation services)/ ability of applicant to perform field evaluation (where relevant)</i></li> <li>&gt; <i>Does SA have a delivery and collaborative environment where the health technology may be introduced?</i></li> <li>&gt; <i>Potential to refer SA patients to interstate public hospitals for the health technology</i></li> </ul>	
<b>Credentialing and Competency</b>	<ul style="list-style-type: none"> <li>&gt; <i>Credentialing of appropriate clinicians; May be completion of course, training, accreditation</i></li> <li>&gt; <i>Considerations for competency and experience with technology – e.g. number of procedures to be undertaken under supervision or number of cases per year or per service.</i></li> </ul>	

**CONSISTENCY WITH EXPECTED SOCIETAL/ ETHICAL/ LEGAL VALUES** (relevant when safety, clinical and cost-effectiveness are met)

<b>Societal/ Ethical/ Legal Values</b>	<ul style="list-style-type: none"> <li>&gt; <i>Broadly shared values in society that bear on the appropriate use and impact of the technology.</i></li> <li>&gt; <i>The potential ethical issues inherent in using or not using the technology.</i></li> </ul>	
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**SAPACT DECISION** (tick one box)

- 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 for clinical adoption. Re-application may be undertaken in the future.
- Not Recommended, subjected to implementation in clinical trial with approval from SA Health Human Research and Ethics Committee.

Comments:

<Comments>

**SIGNATURE:**

**DATE:**

SAPACT Chair

