#### Guideline



# **New Health Technologies and Specialised Services**

**Summary** This document guides NSW Health Organisations in their role in locally evaluating

new health technologies. It outlines the process for reviewing and assessing health technologies that are new to the NSW public health system. It informs how local processes intersects with those of the NSW Ministry of Health, and provides advice on

purchasing decisions for specialty services in NSW Health.

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Pathology, Public Health System Support Division, Cancer Institute

Distributed to Public Health System, NSW Ambulance Service

Audience All Staff of NSW Health





# **New Health Technologies and Specialised Services**

#### **GUIDELINE SUMMARY**

This Guideline outlines the process for review and assessment of health technologies that are new to the NSW public health system. It guides NSW Health organisations in the local evaluation of new health technologies and provides information on when local processes intersect with those of the NSW Ministry of Health.

It outlines the NSW Ministry of Health's processes for purchase of specialty services.

#### **KEY PRINCIPLES**

This Guideline outlines the approach to introduce new health technologies and specialised services in NSW to support contemporary high quality clinical service provision.

The impact of a new technology or clinical service on the health system will determine the most appropriate approach to service planning and provision:

- Local service provision planning by Local Health District/Specialty Health Network to meet the needs of the local population
- Networked service planning by Local Health District/Specialty Health Network but may support other services within a defined clinical network
- Supra-LHD services planning by NSW Ministry of Health as highly specialised services offered by limited sites on behalf of NSW
- National planning highly specialised services for small populations requiring a national approach to planning.

A Local Health District/Specialty Health Network may nominate a new technology to the NSW Ministry of Health for Statewide or national review. The NSW Ministry of Health will follow a prioritisation matrix to analyse and make decisions for the introduction of new health technology for implementation.

Any new technologies recommended for Statewide implementation are considered in the annual service agreement cycle. The NSW Ministry of Health will advise the parameters for Statewide implementation, such as volume, agreed indications and plan for monitoring and evaluation. The Local Health District/Specialty Health Network that provides the service will be responsible for further implementation and planning.

The Chief Executives of NSW Local Health District/Specialty Health Network and Pillar Organisations are responsible for the implementation of this Guideline within their services and facilities. This includes ensuring that local protocols or operating procedures are in place in accordance with this Guideline. All staff are to be aware of the Guideline and actively participate in its implementation.

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### **REVISION HISTORY**

| Version                        | Approved By   | Amendment Notes  |
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| GL2022_012<br>October-2022     | Deputy Secretary,<br>Health System Strategy<br>and Planning | Guideline updated to reflect the contemporary policy environment and changes to the new heath technology nomination process. |
| September 2018<br>(GL2018_023) | Deputy Secretary,<br>Strategy and Resources                 | Revised Guideline  |
| January 2017<br>(GL2017_020)   | Deputy Secretary,<br>Strategy and Resources                 | Revised Guideline  |
| December 2016<br>(GL2017_001)  | Deputy Secretary,<br>Strategy and Resources                 | New Guideline  |



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#### **New Health Technologies and Specialised Services**

#### 1. BACKGROUND

A health technology is an intervention that may be used to promote health, to prevent, diagnose or treat acute or chronic illness, or for rehabilitation<sup>1</sup>. It may take the form of a medical device, procedure or process of clinical management which is substantially different from the alternative.

NSW Health is committed to delivering outcomes and experiences that matter to patients and the community. Health technologies play an important role in driving value-based healthcare<sup>2</sup>, which means continually striving to deliver care that improves:

- health outcomes that matter to patients
- experiences of receiving care
- experiences of providing care
- effectiveness and efficiency of care.

A shift from outputs to outcomes aligns with the <u>NSW Government's Outcome Budgeting</u> reforms for Whole of Government. This has a long-term impact on how services will be planned, funded and delivered in the future.

Decisions made regarding the introduction of new health technologies in NSW need to be balanced by the available evidence, cost implications and the requirement of the health system to provide contemporary high quality clinical services across all areas of service provision. Health system priorities and community need in other areas of health service provision will also be considered.

Local and Statewide implementation of new health technologies requires different levels of supporting evidence, and funding models. Innovations in health care are to move from bench to bed-side and on to Statewide adoption as the evidence supporting their use matures.

#### 1.1. About this Document

NSW Health supports innovation at the local level and Local Health Districts (Districts)/ Specialty Health Networks (Networks) may choose to implement new health technologies or provide services locally that are not adopted for use at a Statewide level. In these instances, these services are provided with Districts/Networks resources.

The principles of technology assessment and implementation presented in this Guideline are applicable for all technologies and must be used when considering whether to introduce any new technology to local patient care pathways.

The NSW Ministry of Health (Ministry) considers a subset of health technologies for Statewide adoption. Technologies listed as out of scope for Ministry consideration (section 4.1) are ones that fall under the responsibility of other agencies or organisations.

<sup>&</sup>lt;sup>1</sup> HTA Glossary.net. Available from: http://htaglossary.net/health+technology

<sup>&</sup>lt;sup>2</sup> Value based healthcare. Available from: <a href="https://www.health.nsw.gov.au/Value/Pages/about.aspx">https://www.health.nsw.gov.au/Value/Pages/about.aspx</a>



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The Ministry adheres to a defined process for the analysis, prioritisation, and purchasing of new health technologies. Refer to Figure 1 for an illustration of these processes and their intersection points.

Figure 1: Local and Statewide processes for introduction of a new health technology

#### Introduction of a new health technology in NSW Health Ministry process for statewide implementation Purchasing options Refer to national health technology processes Advice to Advice to Disinvestment the Secretary the system Process for local implementation Local implementation Information sharing to assist Local Health Districts/Speciality Networks with local decision making New technology potential Identify and projects identified investigate mittee Outco Local committee assess Assess proposals Submit No further action Technology is out of Out of scope / scope. Effectiveness not demonstrated. Referred to appropriate agency (e.g. eHealth) Allocation of resources to **Technologies** Technology NOMINATION and Speciality planning implement locally Not enough clinical Archive pending advice Implement to assess safety, implementation plan Still in research from system efficacy and cost-effectiveness for public funding. Monitoring and Local data collection and · Further advice is sought Technology has been found to have some benefits, but more e.g. Health Technology Assessment, Evidence Review, referral to Seek further information needed. national health technology processes Technology has been found to be safe, effective and cost effective. Negotiation on purchase options NSW population would benefit from provision of service.

# 1.2. Role of the NSW Ministry of Health in planning

The Districts and Networks are responsible for planning services that are responsive to the needs of their local population. The Ministry is responsible for co-ordinating the planning of services to meet the needs of the NSW population. The Ministry also has a role in informing national health initiatives and coordinating the NSW system response to these initiatives.

The Ministry's role in planning lies along a continuum from setting broad directions in healthcare provision to leading specific planning processes such as the planning and oversight of specialised services<sup>3</sup>.

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<sup>&</sup>lt;sup>3</sup> Corporate Governance Planning and Accountability compendium: http://www.health.nsw.gov.au/policies/manuals/pages/corporate-governance-compendium.aspx.



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#### 1.3. Planning for Specialised Services

Planning future capacity for NSW Health services is underpinned by robust clinical service planning that considers service demand over the next 10 – 15 years and factors including:

- Target population projections
- · Age, sex, morbidity of patient groups
- · Changing trends in patterns of disease and treatment
- Statewide priorities
- Affordability and value
- Development of new models of care
- Quality and safety considerations
- Availability of skilled workforce
- Climate risks.

NSW Health has a range of planning tools, guidelines and methodologies to estimate future demand and support the planning of health services. This includes the Clinical Services Planning Analytics (CaSPA) which is available to NSW Health planners.

The impact of a new technology or clinical service on the health system will determine the most appropriate approach to service planning and provision (see Figure 2). This ranges from a Districts/Networks managed service for their local population up to highly complex, small volume services that require a national population for safe and effective service provision.

The new health technologies framework represents a coordinated approach to the assessment of technologies to support a transparent process for the planning and purchase of new health technology in NSW.



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Figure 2: Approach to specialised service planning in NSW



### 2. LOCAL PROCESS

This section outlines the suggested process for Local Health Districts (Districts)/Specialty Health Networks (Networks) introduction of a new technology and refers to local implementation only.

The NSW Ministry of Health (Ministry) encourages Districts/Networks develop local processes to identify, assess, fund and evaluate new health technologies to ensure a robust approach to innovation.

The Ministry proposes a five-step process to effectively progress new health technologies in a framework that does not compromise patient safety or quality of care:

- 1. Identify and investigate
- 2. Assess
- 3. Service planning
- 4. Implement
- 5. Monitor and evaluate.

## 2.1. Identify and investigate

A new health technology may be identified by local clinicians for implementation within their District/Network. This can occur through a number of channels, including:

Formal state and national processes



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- Licensing and reimbursement agencies, i.e., the Therapeutic Goods Administration (TGA)
- · Published literature and conference proceedings
- Experts and expert groups, including professional associations
- Technology manufacturers.

Once a technology has been identified, it is recommended that a formal proposal is developed to enable a robust assessment and evaluation. This must include the justification for the introduction of the new technology. Proposals must address the points outlined in Table 1.

To assist with this process the Districts/Networks may wish to refer to the Ministry's New Health Technology Nomination form. The form is used by the Ministry to guide the submission of annual nominations of new technologies for Statewide implementation through its new health technology evaluation process and can be adapted by Districts/Networks for local use.



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Table 1: Local New Health Technology proposals, suggested inclusions

| Table 1: Local New Health Technology proposals, suggested inclusions   |   |  |  |  |
|--|---|--|--|--|
| New Health Technology Prop   | Resources   |  |  |  |
| Justification and Rationale  1. A rationale for the introduction of the technology at a local level, including local clinical need, benefits compared to current treatment approaches and evidence to support the proposed change. | Clinical Evidence  Quality, value and impact of scientific evidence.  Potential impact on patient and provider experience.  Anticipated outcomes including, length of stay, readmission rate quality of life impacts and morbidity and mortality rates.  Acceptability of the technology.   | It is recommended that a hierarchy of evidence be applied. Established guidelines may be useful, such as:  • TGA Evidence Guidelines  • National Health and Medical Research Council (NHMRC) Guidelines for guidelines |  |  |
|  | <ul> <li>Impact on efficiency and effectiveness</li> <li>Potential impact of the new technology on efficiency and effectiveness.</li> <li>Cost-benefit analysis including operating costs, capital and equipment requirements, workforce requirements and any offsets or saving compared to current practice.</li> <li>Opportunities for service reconfiguration with the introduction of the new health technology, including potential savings or enhancements in service delivery through changes to practice or model of care.</li> <li>Disinvestment opportunities.</li> </ul> | Agency for Clinical Innovation<br>Implementation Supports  |  |  |
| Service Proposal  2. Information on how the technology will be introduced, including proposed target population, selection criteria and anticipated volume   | <ul> <li>Mapping of the proposed patient pathway and care model.</li> <li>Expected impact on other clinical and supportive services.</li> <li>Safety requirements relating to the technology's introduction, including training and credentialing requirements, infection prevention and control.</li> <li>Identification and review of any conflicts of interest and areas of potential bias         <ul> <li>e.g., manufactures/supplier.</li> </ul> </li> </ul>  |  |  |  |
| Monitoring and Evaluation  | <ul> <li>Planned approach to monitoring<br/>and evaluation.</li> </ul>  | NSW Government Evaluation<br>Guidelines  |  |  |



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#### 2.2. Assess

It is recommended that each District/Network have a locally established process, with clearly defined governance, for the review, assessment, approval and oversight of the implementation of new health technologies. This may be a specialised committee established for the sole purpose of new health technology assessment/evaluation, or an additional function of an established committee such as the Local Clinical Governance Committee.

The Committee may need to prioritise technologies for local review or adoption. The District/Network may wish to refer to the Ministry's *Prioritisation and Assessment Matrix* (appendix 2) to assist with this process. The matrix is used by the Ministry to prioritise nominated technologies and may be adapted for local use.

Once the Committee has agreed to proceed with the introduction of a new technology, it is recommended that final sign off be sought through the Districts/Networks Chief Executive or their delegate.

## 2.3. Service planning

The local committee overseeing the introduction of a new health technology must ensure responsibility and accountability for the planning and implementation is assigned to a specific team. This team will be responsible for risk assessment and management. The implementation team are to regularly report progress of the introduction of the new technology across the Districts/Networks to an executive sponsor.

The implementation team are to consider:

- Whether the role delineation of the service aligns to the requirements of the new health technology
- The impact that introduction of the new health technology may have on the configuration of local service delivery and model of care
- Funding allocation/reallocation strategies, including the identification of finances, disinvestment and savings opportunities
- Access to adequate education and training for staff and/or identifying staff that are appropriately trained to use the new health technology
- Technology and infrastructure requirements, ensuring there are strategies for reviewing and facilitating any necessary changes or introduction of new fixtures and/or equipment
- Development of clinical pathways and/or protocols which may include consent procedures, clinical protocols, patient referral requirements, approaches to transfer of care and follow-up and communication pathways with referrers including Primary Health Networks (PHNs)
- Developmentment of appropriate consumer literature and information
- When establishing a new service, or introducing a new technology into an existing service, Districts/Networks are encouraged to consider opportunities for future publication of outcomes. Early applications to local ethics



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committees will enable clinicians to effectively contribute to the national and international evidence base.

#### 2.3.1. Risk assessment and management

The risk assessment and management process is integral when considering implementation of a new technology, procedure or service and must be:

- · Tailored to the specific activity and environment
- Transparent and inclusive
- · Responsive to change
- Actively promoting continuous improvement
- Considerate of ethical, human, cultural and climate factors, in line with Statewide and local ethical processes as outlined in the NSW Health Guideline Human Research Ethics Committees - Quality Improvement & Ethical Review: A Practice Guide for NSW (GL2007\_20).

To assist with this process, Districts/Networks can refer to the risk management process described in <u>AS/NZS ISO 31000:2018 Risk Management – Guidelines</u>. These guidelines introduce the 11 principles of risk management and a generic framework for assessing, treating and prioritising risks and opportunities.

Any risk assessment conducted must be in line with the NSW Health Policy Directive *Enterprise-wide Risk Management* (PD2022 023).

#### 2.4. Implementation

An implementation plan must be developed to direct the work of the implementation team. All stakeholders, including clinicians and managers, may inform the work of the implementation team to ensure that the safety and effectiveness of the technology is maximised.

Any new risks that are identified during the implementation phase can be addressed through mitigation strategies developed by the implementation team.

#### 2.5. Monitor and Evaluate

Program monitoring and evaluation must be undertaken to measure the impact of the new technology across the four dimensions of value-based healthcare, including *health outcomes* that matter to patients, experiences of receiving care, experiences of providing care and effectiveness and efficiency of care<sup>4</sup>. The <u>NSW Government Program Evaluation Guidelines</u> are to be used to guide this process.

A monitoring and evaluation plan must be developed to guide implementation of the new health technology and allow continuous assessment and optimisation of service delivery as required. The four dimensions of value-based healthcare must inform the evaluation

Value based healthcare. Available from: <a href="https://www.health.nsw.gov.au/Value/Pages/about.aspx">https://www.health.nsw.gov.au/Value/Pages/about.aspx</a> [Accessed March 2022]
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approach and provide the basis for identifying the data collection requirements for monitoring and evaluation.

Process evaluation may identify opportunities for optimisation in the use of the new health technology. Opportunities for optimisation could include additional education and training of staff as well as assessment and review of the clinical scope of the technology over time as the evidence and expertise regarding the use of the new health technology develops.

Changes to practice must be endorsed by the local committee that originally assessed and approved the new technology prior to any changes being applied.

Outcome evaluations can be used to measure the impact of the technology against the four dimensions of value-based healthcare. It can be used to identify who the technology benefits, to what extend and under what circumstances, and identify any unintended consequences.

New health technologies are to be subject to pre-specified stopping criteria agreed at the time of approval by the local assessment committee. The development of trigger incidents specifically related to the new health technology may be of use as a part of this process. The Director of Clinical Governance must be notified immediately if the stopping criteria are met. The decision to recommence the new health technology may be based on the outcome of the incident/adverse event review investigation and with the approval of the Chief Executive.

# 3. STATEWIDE ASSESSMENT AND IMPLEMENTATION PROCESS

There are significant differences in the level of evidence required to implement a new health technology at a local level, compared to a system level implementation and adoption across multiple sites. The NSW Ministry of Health (Ministry) has a formal process for notification, assessment, prioritisation and purchasing of new technologies which is described in the following sections.

Local Health Districts (Districts)/Specialty Health Networks (Networks) can engage with the Ministry's assessment and implementation processes by submitting a new technology nomination for review by the New Health Technology and Specialised Services Committee (Committee).

## 3.1. New technology nomination

Health technologies that are new to the NSW public health system and meet the following criteria may be nominated to the Ministry by the Districts/Networks or pillar for review and assessment in the following circumstances:

- Technology is new to NSW
- Technology may have significant positive system impacts if adopted across NSW
- Volume/quality outcome relationship for the technology supports a case for service concentration, i.e., a Statewide population is needed for safe, effective and efficient service delivery



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- Technology is highly specialised and likely to be low volume, i.e., will only be provided in a limited number of locations
- · Limited/highly specialised workforce is required
- Significant infrastructure is required
- There are other factors that elevate the new health technology out of local planning/budgeting capacity, such as specific specialised technical requirements or significant financial investment
- Technology represents a significant opportunity to reduce and/or replace
  existing redundant technologies, as well as the potential offsets of the new
  technology within the same model of care, e.g., reduced length of stay.

Additionally, technologies may be identified to the Ministry through a number of other channels, including:

- Advice from the Committee
- National and jurisdictional health technology processes, e.g., high-cost therapies and services through the addendum to the National Health Reform Agreement 2020-25
- Clinical networks and work program of pillars
- Regular performance meetings between the Ministry and Districts/Networks
- Local health technology evaluation processes.

Technologies may be identified for assessment of Statewide application if they are transitioning from the research phase into clinical practice or are established technologies that are new to the NSW public health system.

Technologies still in the early stages of development must be investigated via an ethicsapproved research study and are therefore not appropriate for consideration by the Committee.

**In-scope** technologies for Ministry level consideration are:

- Implantable devices
- Medical and surgical procedures
- Treatment and diagnostic technologies
- Technologies nominated for disinvestment
- Genetic markers, gene-based diagnostics or gene and cell therapies
- The use of existing technologies for applications not adequately supported by clinical evidence, e.g., new or emerging indications.

Out-of-scope technologies are considered to be:



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- Medicines<sup>5</sup>, including radiopharmaceuticals
- Information and communication technologies (ICT)
- Public health activities and programs
- · Primary health technologies
- Technologies not approved by the Therapeutic Goods Administration (TGA)6.

Nominations can be submitted at any time for review by the Committee at their March, August and November meetings. Submissions received within four weeks of a Committee meeting will be held over to the following meeting.

All nominations must be approved by the Chief Executive of the NSW Health organisation. Nominations will not be accepted from individual hospitals or clinicians.

### 3.2. The New Technology and Specialised Services Committee

In NSW a coordinated approach to the assessment of health technologies underpins the introduction of technologies that are **new** to the NSW public hospital system.

The Committee is an expert advisory group established to facilitate planning and prioritisation of specialised services in the system.

The Committee provides strategic oversight of the Ministry's new health technology and specialised services process, including:

- Prioritising nominations of new health technologies to determine those for further consideration or assessment
- Advising on emerging health technologies that may impact NSW
- Advising on opportunities for disinvestment
- Making recommendations to the Secretary, NSW Health regarding the purchasing of supra LHD or specialised services
- Making recommendations to the Secretary regarding services that require transitioning from a supra LHD to a networked service.

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Medicines are excluded due to existing processes in place within NSW. A process for off-label use of unapproved drugs (including radiopharmaceuticals) is set out in <u>Approval Process of Medicines for Use in NSW Public Hospitals</u> (PD2016\_033). Hybrid technologies such as drug eluting stents are considered by the committee.

<sup>&</sup>lt;sup>6</sup> As a general principle, the routine use of non-TGA approved products outside of a dedicated clinical trial is not supported in NSW public health facilities. However, it is acknowledged that there are some technologies that will not have or require TGA approval (e.g. islet cell transplantation) or may not be amendable to clinical trials. In such cases, there may be a need to consider such technologies through the New Technologies Committee. This may include those that are being routinely used under the Special Access Scheme and Importation for Personal Use or Authorised Prescriber schemes.



#### **New Health Technologies and Specialised Services**

The membership of the Committee includes:

| NSW Health Organisation            | Committee Member Position  |  |
|------------------------------------|--|--|
| NSW Ministry of Health             | <ul> <li>Deputy Secretary, Health System Strategy and Planning (Chair)</li> <li>NSW Chief Health Officer</li> <li>Deputy Secretary, Patient Experience and System Performance Division</li> <li>Executive Director, Strategic Reform and Planning</li> <li>Executive Director, Office of Health and Medical Research</li> <li>Director, Specialty Service and Technology Evaluation</li> </ul> |  |
| NSW Agency for Clinical Innovation | Chief Executive  |  |
| Cancer Institute NSW               | Chief Executive  |  |
| Clinical Excellence Commission     | Director, Clinical Governance  |  |
| Health Infrastructure              | Executive Director, Assets, Development and Innovation   |  |

Advice will be sought from NSW Health Pathology and eHealth NSW and subject matter experts as required.

The work of the Committee is coordinated by the Ministry. Where necessary, the Ministry may engage expertise in core areas such as health technology review and assessment, bioethics, epidemiology, health economics, and clinical and medical research expertise.

Any further technology assessment identified as necessary by Committee members will also be progressed by the Ministry and may consider demand analysis, cost effectiveness or workforce requirements. Where identified, the nominated technology may also be referred to national technology assessment bodies for review and/or advice (appendix 1).

#### 3.3. Assessment of nominations

During the assessment process the Committee can:

- Seek further information or assessment of the technology
- Refer to the Nationally Funded Centres (NFC) Program for very low volume, high cost and highly specialised services
- Recommend a service is purchased as a supra LHD or networked service to the Secretary, NSW Health.

The Committee's review process considers available evidence to inform advice, including but not limited to:

- Leveraging relevant national and jurisdictional processes in health technology review and assessment (appendix 1)
- Consideration of previous health technology assessments, clinical and funding information and reviews
- Advice from the relevant NSW Health pillar(s).



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Devices that have been awarded funding or supported through the Medical Device Fund can be submitted for consideration by Districts/Networks to the Committee. They will be subject to the same approval and prioritisation processes.

A matrix is used by the Ministry and the Committee to assess applications against agreed criteria (appendix 2). The Committee may decide to engage in further assessment via health technology review or consultation with subject matter experts. Following full assessment, applications will be provided with one of five outcomes (table 2).

In the event that Districts/Networks have nominated a new technology that is later considered for Statewide purchasing, they may be required to enter into a competitive expression of interest process to be considered as the service provider.

Table 2: Statewide health technology evaluation outcomes

| Outcome             | Definition   | Action  |  |  |
|---------------------|--|---|--|--|
| Out of scope        | The technology is out-of-scope (section 4.1) or the nomination is for local District/Network use only  |   |  |  |
| Not Recommended     | Health technology has not demonstrated benefit in terms of experience, outcomes or effectiveness and efficiency compared to standard treatment   | Archive technology  |  |  |
| Still in Research   | Not enough clinical evidence is available to assess experience, outcomes or effectiveness and efficiency compared to standard treatment  | District/Network may use the technology under a research/evaluation framework.  May consider a further application when more evidence is available. |  |  |
| Seek Further Advice | Technology has been found to have some benefits in certain population groups, but more information is required to form a recommendation  | Further advice and/or technology assessment sought  |  |  |
| Recommended         | Health technology has proven benefit in terms of experience, outcomes and effectiveness and efficiency compared to standard treatment. NSW population would benefit from provision of service. | Negotiation on service delivery and purchasing options  |  |  |

#### 3.3.1. Dissemination of new technology nominations

The Ministry will share a summary of nominations on the <u>New Health Technologies</u> webpages which are housed on the NSW Health Intranet and public-facing internet pages. The purpose of this is to increase knowledge and facilitate collaboration in the system.

Following the assessment process, the Ministry will draft a summary of the technology. Unless permission to disseminate is withheld on the nomination form. Final sign off for any web content will sit with the Deputy Secretary, Health System Strategy and Planning.



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# 4. PURCHASING AND MONITORING OF TECHNOLOGIES AND SPECIALISED SERVICES

Once a technology has been recommended for Statewide purchasing by the New Health Technology and Specialised Services Committee (Committee), there is an established process to review and negotiate purchasing options.

## 4.1. Approval Process – Recommended technologies

Recommendations for Statewide implementation made by the Committee requires approval from the Secretary, NSW Health, before proceeding with purchasing negotiations.

The Secretary is provided with supporting evidence to assist with the approval process. This includes clinical need, effectiveness, feasibility, and ethical and equity considerations.

If implementation is approved by the Secretary, the NSW Ministry of Health (Ministry) will lead a process to determine the purchasing approach for that technology. The following sections provide an outline of this process.

# **4.2.** Purchasing of new technologies and specialised services for Statewide provision

All new technologies recommended for Statewide implementation are considered in the annual service agreement cycle managed by the Ministry's Patient Experience and System Performance Division. All purchasing decisions are made in the context of the overall NSW Health budget. Purchasing decisions will focus on system issues such as number of sites required, geographic location, infrastructure and equipment requirements, workforce considerations, and evidence-based patient selection criteria.

The Ministry will advise the parameters for introducing the new health technology, such as volume and agreed indications. The Local Health Districts (Districts)/Specialty Health Network (Networks) tasked with providing the service will be responsible for further implementation and planning, including clinical requirements, service delivery, staffing, monitoring and evaluation.

It is to be noted that where a district/network has nominated a new technology that is later considered for Statewide purchasing consideration, they may be required to enter into a competitive expression of interest process to determine the service provider.

Purchasing models for new technologies in NSW fall into two broad categories:

Supra LHD service: Supra LHD services are provided across District/Network boundaries and are characterised by a combination of the following factors:

- Services are provided on behalf of the State that is, a significant proportion of service users are from outside the host District/Network catchment
- Services are provided from limited sites across NSW
- Services are high cost with low-volume activity
- Individual clinicians or teams in supra LHD services have highly specialised skills



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Significant investment in highly specialised infrastructure is required.

Supra LHD Services are assigned a Clinical Lead, e.g., the Cancer Institute NSW, who is responsible for identifying issues such as changes to clinical evidence and model of care that may influence current and/or future demand.

#### New service

Time-limited funding and/or managed diffusion prior to widespread use.

Technologies/services for limited introduction may be transitioned into a new Supra LHD Service following initial introduction, or where a national population base is required, the service may be considered for submission through the Nationally Funded Centres (NFC) process (appendix 1).

#### 4.2.1. Ongoing purchasing of established supra LHD services

Strategic Reform and Planning Branch will provide advice to the Patient Experience and System Performance Division to inform the purchasing decisions for supra LHD Services during the annual service agreement negotiations with the host District/Network. This process will be adapted for each supra LHD service in discussion with the relevant clinical lead.

# 4.3. Transitioning from supra LHD status to a networked service

The data obtained for the monitoring and evaluation will be used to determine whether supra LHD services continue to meet the criteria outlined above. If the service becomes more diffuse in the health system, it may be considered for transition to a networked service. Networked services are those provided under networked clinical arrangements and are provided at a greater number of sites than supra LHD services.

The planning, funding and service delivery considerations for networked services sit with the host District/Network but the service is still provided for patients from across the State. A number of service users will therefore be from outside the host District/Network catchment.

The transition from supra LHD service status to a networked service is based upon a review of the specific performance indicators, such as Statewide access and service volumes and following discussion with the clinical lead and service provider. The final recommendation for a service to transition to a networked service will be made by the Committee to the Secretary.

Following approval to transition to a networked service there may be a need to monitor the service in the short term to ensure that activity and access to the service remain stable.

The process for transitioning a supra LHD service to a networked service will be transparent to ensure that the leverage associated with supra LHD service status is retained. This will include the expectations of the system with regard to supra LHD service provision and access. The movement of services on and off supra LHD service status supports a dynamic process for the uptake of new technologies and a culture of performance monitoring.



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#### 4.4. Monitoring and evaluation

Monitoring and evaluation are critical elements to assess the impact of the technology in relation to clinical outcomes, patient experience, cost effectiveness, and equity of access.

As with local technology assessment recommendations, the Ministry will develop a monitoring and evaluation plan that measures the impact of the technology across the domains of experience, outcomes and effectiveness and efficiency.

Health outcome evaluation is included as a way of monitoring the longer-term impact of the new health technology on relevant health outcomes and quality of life. Evaluation methodology is guided by the <a href="NSW Government evaluation guidelines">NSW Government evaluation guidelines</a> primarily through the co-ordinated use of process and outcome evaluation.

Reporting will be aligned to existing data collections to minimise additional reporting requirements. Reporting requirements may need to expand in some cases depending on measures outlined in the monitoring and evaluation plan (e.g., efficiency, carbon reporting etc).

The Districts/Networks are responsible for service level monitoring consistent with local policies and procedures for Clinical Governance. This includes clinical aspects, adverse events and patient outcomes. Any proposed expansion to the agreed clinical indications will require review, and approval, by the Ministry, Clinical Lead (for supra LHD services) and Service Providers.

Projected service demand assumptions outlined in the plan are to be reviewed regularly against activity data to minimise deviation.

#### 4.4.1. Annual reporting for supra LHD services

The Ministry is piloting annual reporting requirements with a sub-set of supra LHD services. The purpose of the reporting is to ensure services are meeting the expected outcomes, providing effective, Statewide access and still meet the characteristics of a supra LHD service. The annual report will also provide an avenue to report any changes in model of care or updates to technology which may alter service delivery.

#### 5. LINKS TO NATIONAL HEALTH TECHNOLOGY PROCESSES

National health technology governance structures are undergoing major reform. The NSW Ministry of Health (Ministry) will continue leverage interim processes where appropriate until the formal transition to new governance arrangements is finalised.

#### 5.1. National Health Reform Agreement 2020-2025

The implementation of high cost, highly specialised therapies is governed by the National Health Reform Agreement (NHRA) 2020-2025. The Addendum to the National Health Reform Agreement 2020-2025 includes arrangements to oversee the assessment and funding of high cost, highly specialised therapies. Under the National Health Reform Agreement these therapies will be funded at a 50:50 per cent State/Commonwealth split.

NSW Health is leading the development of a framework to implement the clauses of the Addendum to the National Health Reform Agreement related to high-cost therapies. The



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framework will support equitable access to high-cost therapies and facilitate implementation, monitoring and evaluation of these therapies to ensure the anticipated health outcomes and cost-effectiveness are achieved.

## **5.2.** Nationally Funded Centres Program

The Nationally Funded Centres (NFC) Program is a national program convened under the former Australian Health Minister's Advisory Council (AHMAC). The Nationally Funded Centres provides access to high cost, low volume services that require a national population base for effective and efficient delivery. The program is funded by the states and territories on a population share basis.

Existing programs under the Nationally Funded Centres will continue to operate under the former guidelines until national processes are finalised.



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#### 6. APPENDICES

- 1. NSW Health New Technology Nomination Form
- 2. NSW Health Technology and Specialised Services Strategic Forum Prioritisation & Assessment Matrix



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### 6.1. NSW Health New Technology Nomination Form

NSW Health invites Chief Executives of Local Health Districts/Specialty Health Networks and NSW Health pillars, and Deputy Secretaries of the Ministry to submit a *New Technology Nomination* for review by the NSW Health Technology and Specialised Services Committee.

Nominations are sought for health technologies with potential to significantly impact the NSW healthcare system and/or those that would benefit from further health technology review.

The NSW Health New Technology Nomination Form is available on the <u>NSW Health</u> website.

#### General requirements for nominations:

- All materials accompanying an application must comply with privacy and intellectual property principles and regulations
- Information identifying individual patients is not to form any part of the application
- Applicants understand that by submitting an application, all confidential, personal or proprietary information included are subject to the provisions of the <u>Government</u> <u>Information (Public Access) Act 2009</u> (NSW)
- Applicant must obtain manufacturer consent for information provided in applications submitted to NSW Ministry of Health
- Summary outcomes will be posted on the NSW Health Intranet new technologies site following approval by nominating chief executives.

#### Note:

- Nominations will only be accepted from the chief executive of a NSW Health pillar, district, network, or a Deputy Secretary NSW Ministry of Health.
- Nomination is the initial process in consideration of new technologies. If the nomination is prioritised for further consideration, more detailed information will be requested.
- If you have any further queries regarding the completion of this form, please email: MOH-HealthTechNominations@health.nsw.gov.au.
- Completed nomination forms can be emailed to: <u>MOH-HealthTechNominations@health.nsw.gov.au</u>.



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# 6.2. NSW Health Technology and Specialised Services Strategic Forum – Prioritisation & Assessment Matrix

The Matrix is used by NSW Ministry of Health (the Ministry) and Health Technology and Specialised Services Strategic Forum to assist in the prioritisation of nomination technologies for further consideration: the higher the score, the higher the ranking.

Thorough review of clinical effectiveness, safety, assessment of current therapies, and cost effectiveness will be considered in the detailed health technology project if the nomination is prioritised to proceed to the next stage. The Matrix may be used locally or adapted for local use.

| Principle            | Definition/considerations  | Circle | Score descriptor  |
|----------------------|--|--------|---|
| Clinical<br>Need     | The burden of illness of the target condition the technology applies to  - e.g., incidence, prevalence, Years of Life lost, Disability Adjusted Life Years.  Availability of alternative therapies to treat the nominated condition. | 3      | Significant burden of illness, limited availability of alternate therapies/diagnostics  |
|                      |  | 2      | Average burden of disease, some alternative therapies/diagnostics available though not optimal (significant side effects, inpatient therapy v outpatient) |
|                      |  | 1      | Less significant burden of illness, other clinically and cost-effective therapies/diagnostics available   |
| Materiality          | The technology has the potential to make a material impact or significant difference in outcomes for the environment, health system, the health service provider and/or the patient outcomes and experience.                         | 3      | High likelihood of material benefit.  |
|                      |  | 2      | Average material impact.  |
|                      |  | 1      | Limited likelihood of material benefit.   |
| Economic Feasibility | Likely level of investment  - i.e., managed within existing LHD resourcing or requiring investment from the Ministry or others.  | 3      | Likely to require Ministry and Other investment - e.g. Commonwealth   |
|                      |  | 2      | Likely to require Ministry investment/resourcing  |
|                      |  | 1      | Likely to be managed from within existing LHD/SHN resourcing  |
| Equity               | Statewide purchasing approach through the public hospital system necessary for equity of access for the target population.   | 3      | Likely to be a highly specialised service in limited locations providing equitable access   |
|                      |  | 2      | Time-limited Ministry planning may benefit equity of access.  |
|                      |  | 1      | Technology likely to broadly diffuse in the system via local planning and clinical decision-making  |



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| Principle  | Definition/co  | onsiderations | Circle  | Score descriptor  |
|--|--|---------------|---|---|
| Level of Evidence Current level of evidence for the technology.  Assessed according to the |  | 3             | High. Evidence provided is of high quality with low risk of bias. Very confident that clinical claims are supported.                |   |
|  | population available and the level of experience using the technology. | 2             | Moderate. Evidence provided is of moderate quality with some risk of bias. Moderately confident that clinical claims are supported. |   |
|  |  | 1             | Low. Evidence provided is of low quality with high risk of bias. Limited confidence that clinical claims are supported              |   |
|  |  |               | 0.5   | Very Low. Quality of evidence is insufficient to support clinical claims.   |
| Policy<br>Congruence   | 2  |               | 3   | Aligns with government, Ministry and/or NSW Health policy and/or priorities   |
|  |  |               | 2   | Aligns with government/Ministry priorities, change in NSW Health policy may be required to accommodate the technology |
|  |  |               | 1   | Not aligned with government, Ministry and/or NSW Health policy and/or priorities                                      |
|  |  | TOTAL SCORE   |   |   |