



# SelectHealth<sup>SM</sup> Medical Technology Assessment Program

**"It is always too early to evaluate until suddenly it is too late." Buxton's Law**

Medical technology assessment (MTA) is a systematic process for evaluating the characteristics, effects, and impacts of a health care technology to form a conclusion about the merits of a particular technology in relation to its possible use in clinical practice. SelectHealth<sup>SM</sup> conducts a formal process for reviewing emerging health care technologies to inform medical policy and benefit coverage decisions. This web site outlines the conceptual basis behind the technology assessment process and describes the process of developing medical coverage policies. Various resources related to health care technology assessment are provided.

## What is “Medical Technology”?

SelectHealth evaluates a variety of medical technologies including:

- Medical devices or equipment
- Surgical procedures
- Medical procedures
- Pharmaceuticals
- Biological products

## Rationale for Medical Technology Assessment

Over the last several decades healthcare costs have experienced staggering and continuous cost increases. Paralleling this increase in cost and the associated difficulties in affordability for health care has been an explosion in new and expensive medical technologies. While the exact relationship between the growth in medical technologies and rising healthcare costs is

unclear, what is certain is that new medical technology is typically more expensive than the current standard of care. The added expense of adopting new technologies is usually passed onto patients in the form of higher provider fees and larger insurance premiums. Consequently, medical providers and insurance companies have a **fiduciary responsibility** to patients to ensure they are receiving the most cost-effective, evidence based care possible.

Reimbursement for unproven technologies not only increases cost to patients, but also has the potential to reduce the quality of care they receive, if the technology is not as effective as the present standard of care. In some cases, the application of an unproven medical technology may actually lead to greater harm than good. Consequently, medical providers and insurers also have an **ethical responsibility** to patients to assure they are receiving medical care that has a demonstrated record of safety and effectiveness.

SelectHealth's Medical Technology Assessment Program attempts to meet these two responsibilities by rigorously evaluating emerging medical technologies before determining its coverage policies. We also make these technology assessments and medical policies available to medical providers.

## **Aims of Medical Technology Assessment**

Medical technology assessments typically address the following broad issues related to a particular technology:

- ***Description of the technology*** – design, procedures for use, maintenance, known and theoretical mechanisms of action, patient population and medical conditions where the technology would likely be applied.
- ***Patient safety*** – probable risks to patients and providers from using the technology in clinical practice.
- ***Efficacy and effectiveness*** – benefit of a technology when used under ideal conditions such as in a randomized controlled trial (efficacy) and benefit of a technology when used under typical conditions such as routine clinical care (effectiveness)
- ***Economic impact*** – anticipated financial impact to member premiums, potential cost offsets (savings) from improved health, more accurate or earlier diagnosis, etc, potential for revenue enhancement from clinicians

- ***Ethical, legal, and social issues*** – the potential for application to have broad societal impact beyond its application with an individual patient

## Principles Underlying Medical Technology Assessment

Each technology assessment follows the same underlying steps:

### 1. Identify assessment topics

Any medical technology may be evaluated, but some technologies are more likely to be addressed than others. Requests from local providers or patients to cover a particular technology are common reasons for initiating a technology assessment. Occasionally, media reports on a new technology will prompt an assessment. SelectHealth also subscribes to various medical publications and forecasting services that provide notification of emerging medical technologies.

### 2. Specify the assessment problem

Each assessment outlines a specific question or questions that will be addressed by the evaluation. These may include questions regarding equivalence of technologies (e.g., “how to the outcomes of Treatment A compare with Treatment B?”), clinical utility (e.g., “Does the information provided by Test A provide information that is likely to impact treatment?”), clinical role, (e.g., “Where does Treatment A fit with the currently available treatment options for this condition?”), or cost-effectiveness (e.g., “Is the benefit of Treatment A worth the costs?”). Often, a technology assessment will address multiple questions as part of the evaluation.

### 3. Retrieve evidence

We use a variety of resources to locate evidence regarding the merits of a particular technology. The emphasis is typically on empirical studies published in peer-reviewed journals but additional sources of information are also included to ensure comprehensiveness. These resources include:

- Online databases of published literature (e.g., Medline, Cochrane databases).
- Medical reference guides (e.g., UpToDate)
- Food and Drug Administration website
- Technology assessments published by companies, government entities, or third party payers
- Internal claims data
- Local and national experts

- Local practicing clinicians who may be utilizing or have expertise in a particular technology
- Professional society statements
- Advocacy groups
- Manufacturer websites

#### **4. Interpret and synthesize evidence**

Each assessment includes a literature summary in which the validity and reliability of the evidence from the empirical literature is analyzed. Typically, results from prospective randomized controlled trials and systematic reviews are given greater weight than studies using less rigorous designs. Techniques summarizing the literature vary from report to report, but the following issues are typically addressed:

- Strengths and weakness of study methodology such as:
  - Sample size
  - Control groups
  - Participant selection procedures
  - Adequacy of gold standard
  - Length of follow-up
- Study settings
- Potential conflicts of interest from study investigators
- Effectiveness vs. efficacy
- Validity of study outcomes
- Cost-effectiveness

#### **5. Conclusions and recommendations**

Each assessment includes a summary conclusion representing a consensus derived from the compilation of the information presented in the report and a recommendation for coverage.

### **Principles Underlying Coverage Decisions**

- Medical policies are developed & written to maximize health for the majority of plan members/patients; i.e. population-based.
- The burden of proof of (cost) effectiveness sits squarely on the technology.
- SelectHealth considers new medical interventions/technologies "experimental or investigational" until a sufficient quantity of good evidence indicates otherwise.
- Reimbursement decisions are based on the best evidence available to SelectHealth at the time the policy is written.
- SelectHealth is not responsible for funding biomedical research or clinical investigational studies of new medical technologies

## Development of Coverage Criteria

- All technology assessments are reviewed by an internal committee comprised of practicing physicians and other clinicians trained in the principles of evidence based medicine and the analysis of medical literature.
- Fundamental to SelectHealth's evaluation of medical interventions/technologies is satisfaction of the "investigational" & "experimental" status. These terms have been legally defined in our master contract, which represents a legal contract between SelectHealth and those entities (e.g., employer groups and individuals) for which SelectHealth provides services. Satisfaction of these criteria is only the first step in the process to gain approval for reimbursement.
- Second is the need for sufficient evidence to enable patients, their loved ones, and healthcare provider(s) to make informed and responsible decisions about a medical intervention. Such decisions require that the intervention's possible benefits and harms, and the probabilities they might occur, are understood. Put another way, the available evidence must be sufficient to enable appropriately trained, motivated, and impartial people to draw conclusions about the magnitudes of the effects of the treatment, compared with no treatment, on all the health outcomes they consider important. See Eddy, DM. Investigational Treatments: How strict should we be? JAMA, July 16, 1997--Vol. 278(3): 179-85.
- It is important to note here that the focus is on objective and direct health outcomes...outcomes that people can experience and care about, such as life and death, pain, and functionality. It is essential that assessments be carried all the way through to direct outcomes; settling for indirect outcomes (e.g., cholesterol levels, various markers, and quality of life measures) will leave physicians, patients, and their loved ones ignorant of the outcomes the patients & their loved ones truly care about (Eddy). This is the domain of evidence-based medicine (see links, below): research methodology, statistics, and formal decision making techniques.
- The third element is determination of cost effectiveness which, unfortunately, is often not supported by useable data. The only chance of getting control of medical costs, which continue to escalate rapidly, is to link value (as judged principally by patients, their loved ones, and those who pay the bills) to the costs of providing that value...in an explicit manner. No longer are the various stakeholders willing to pay for every medical intervention, no matter what the cost or how small or uncertain the benefit. Cost effectiveness analysis is extremely

challenging, yet offers the only hope of reconciling the public's demand for the best possible health care at the lowest possible cost.

- The fourth element of the coverage decision is satisfaction of business needs. All insurers have finite budgets, funded principally by the premiums paid by its members and their employers, with which to reimburse for health care interventions. If a new technology causes expenses to exceed income, the only recourse for any insurer is to eventually either increase income by raising premiums or reducing expenditures by reducing payments to providers and facilities. Neither scenario is acceptable when the costs driving these occurrences are due to the misapplication of a technology of marginal or no benefit to the overall health outcomes to members

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"Coverage acts like a ratchet, enabling movement in one direction but not the other. Once covered, the use of a treatment can spread without restraint, incentives to do research plummet, and it can become impossible to learn more about a treatment's effects. The permanent loss of information and the potential for wrong decisions justifies that the minimum criteria for knowing a treatment's effects be met (Eddy DM, 1997)."

## **Evidence-based Medicine & Technology Assessment Resources**

### **Technology Assessment Resources**

- [International Network of Agencies for Health Technology Assessment](#)
- [National Health Service \(Great Britain\) Health Technology Assessment Program](#)
- [The University of York: Centre for Reviews & Dissemination](#)
- [Canadian Health Technology Assessment Network](#)
- [Searching the Net \(for reliable medical information\)](#)
- [CRD databases - home](#)

### **Medical References/Primary Literature**

- [Food and Drug Administration](#)
- [IHC Electronic Journal Collection \(full text, on-line\)](#)
- [Evidence-Based Medicine: Core Library for Evidence Based Practice](#)
- [The Cochrane Collaboration](#)

### **Evidence Based Medicine Websites**

- [Bandolier "Evidence-Based Thinking about Healthcare"](#)

- [Centre for Evidence-based Medicine \(Oxford\)](#)
- [AHRQ \(formerly AHCPR\) Evidence-Based Medicine](#)
- [National Institute of Health: Evaluating the Literature](#)
- [EBM Resources \(Peds CCM\)](#)
- [Graduate Certificate in Evidenced-Based Practice](#)
- [National Guideline Clearinghouse](#)

### **Statistics Websites**

- [Statistics resources webpage](#)
- [The Statistics Homepage](#)
- [Stats - Index page](#)

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