Promising Therapy Methodology:
A New Process at HealthPartners for Improving Coverage Decision Making

HMO INNOVATIONS

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Objectives/Goals

The Promising Therapy Methodology was developed at HealthPartners to create a more structured process for collecting and evaluating the scientific evidence; evaluating the outcome of the therapy in question, both alone and when compared with standard therapy; and for rating the therapy in question as promising.

The intent of the process is to assure a rigorous, well-documented evaluation that is available as a record of the decision-making process for internal or external use and to enhance consistency of decision making.

This process developed from a need for evidence-based, consistent, and timely coverage decisions. It was developed specifically for new procedures or technologies for which coverage is increasingly being requested.

Program Details

The Promising Therapy Methodology is a structured process for evaluating requests for services that fall between experimental therapies and standard care. The specific goal of this process is to assist our health plan personnel in the individual case review process and in preparation for future development of a coverage policy.

The Promising Therapy Methodology can be found at the bottom of Figure 1. Medical policy staff and the medical director do the preparation, which includes collection and review of the scientific evidence, information on health outcomes, and the costs of the procedure under review and of other therapeutic options. This information is then displayed on the Promising Therapy grid (Figure 1) and presented and discussed at a medical directors' committee meeting. This committee consists of physicians involved in coverage decision making and other support staff.

The decision whether the evidence presented is good, fair, or insufficient depends on the number of patients studied, number of centers in the study, research methods, time frame during which the evidence was gathered, specific measured outcomes, and source of the evidence. The threshold for grading the evidence is determined by the risk and cost compared with the alternative treatments available.

All technologies on the Promising Therapy list are reviewed periodically to update the literature; during review, the criterion "strength of conclusion" may be reconsidered. At some time, it is assumed that many promising therapies will become standard care. Others will remain unproved or unsuccessful.

Therapies for consideration are selected from specific coverage requests and from other sources, including providers and the literature. These therapies are prioritized by a perceived or anticipated demand for such services. Once a therapy is determined to be promising, a policy is developed and brought to the benefits committee for consideration of coverage. Some therapies that seem promising but have insufficient evidence to recommend for coverage may be considered for outcomes-based reimbursement contracts. Such contracts include shared financial risk with participating research institutions until additional evidence is available.

**Complete and Chronological
Promising Therapy Grid***

Date	Intervention	Quality of Evidence	Health Outcomes	Probability of Success	Cost	Strength of Recommendation	Status for Coverage Consideration
x-x-9x	X Transplant	C All case series 56 cases	1–2	60% 2-yr graft survival 80% 2-yr survival	$100,000 $XXX Annual cost for standard treatment	C	Experimental

* The information in this grid is for the purpose of example only. The information is fictional and not an indication of any actual review process.

Promising Therapy Methodology

Quality of Evidence	Health Outcomes	Strength of Conclusion
A. Conclusions based on randomized, controlled trial (RCT) B. Conclusion based on one of the following (not RCT) → trial using historical or other nonrandomized controls → prospective cohort study → case-control study → meta-analytic study C. Conclusion based on one of the following (not A or B) → an uncontrolled case series → panel consensus → expert opinion	1. Significantly increased life expectancy 2. Restored function to normal levels 3. Improved function 4. Palliative/minimal increase in life expectancy for terminal condition 5. Custodial/cosmetic/convenience	A. Good evidence to support the conclusion B. Fair evidence to support the conclusion C. Insufficient evidence to conclude for or against D. Fair evidence to support the conclusion against E. Good evidence to support the conclusion against

FIGURE 1. **The Promising Therapy grid (*top*) displays the results of evidence collected from information on health outcomes and costs. The Promising Therapy Methodology (*bottom*) presents the methods used to determine whether a therapy will be covered by the health plan.**

Costs

The amount of time and resources devoted to the development of this process has resulted in a more structured approach to these complex decisions and has saved the time involved in evaluating individual requests and reevaluating promising therapies. It is one step in an evolving process of determining best practice and cost-effectiveness for health care services in the future.

Evaluation

This process has resulted in more consistent coverage decisions and greater confidence in understanding the evidence that supports such decisions. It has led to clarification of contract language and to innovative approaches to reimbursement contracts with the providers of promising therapies. It has pointed out the ongoing need for helpful outcomes research and cost-effectiveness studies to use in considering therapeutic options.

The Promising Therapy Methodology relates to more than just new technology. We believe it may be useful in the future for evaluating standard procedures on the basis of new evidence for coverage decisions. It may also be a helpful tool for health care organizations in guiding disease-management programs and clinical decision making. At HealthPartners, this process is intended to guide coverage decisions in a timely fashion.

The Institute for Clinical Systems (ICSI) is a nonprofit organization that provides technology assessment services to many plans in our area. Technology assessment at ICSI is a longer process, has more active physician involvement, and includes a more formal report than our Promising Therapy Methodology process. These reports are typically intended to inform and guide clinical decision making.

Recommendations to Others

Coverage decisions are difficult to make and understand in this environment of increasing costs, increasing technology, increasing expectations, and decreasing trust. Earning trust requires that health plans become more organized, thorough, and explicit about the decision-making process. Health care delivery systems and physicians need to have systems and processes in place that guide clinical decision making and lead to high-quality, cost-effective care. The Promising Therapy Methodology is one component of HealthPartners' ongoing process of making critical decisions that support our mission of improving our members' health and the health of the community.

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