Evaluating Medical Technology and Medicare's Coverage Process

by Steven H. Sheingold, Ph.D., and Sean Tunis, M.D.

Advances in medical technology will be critical to how well this nation achieves its key health policy objectives of expanding access, improving quality, and maintaining an affordable health care system. Advances in medical science and their clinical application have the potential to eradicate some diseases, reduce the burden of others, and improve the process of care. If history is a guide, new technologies also have the potential to rapidly increase medical care costs, forcing us to confront difficult choices between health care and other economic and social goals.

New medical technology will be valuable to the extent that decisions made by all stakeholders promote the rapid diffusion of effective services and eliminate ineffective and inappropriate uses. Those who support using evidence-based medicine when making health care decisions believe that the systematic development, collection, and analysis of good medical evidence can help us balance the cost and quality consequences of new technology. Other groups see evidence-based medicine as an obstacle to the rapid diffusion of technology. Unless a consensus can be reached between these competing positions, our health care objectives may be very difficult to attain.

At the Health Care Financing Administration (HCFA), we understand that health care professionals who want to see rapid application of new technologies, such as novel radiation therapy equipment, may be hesitant to purchase or use new technologies because they face uncertainties about reimbursement. At the same time, we believe that careful evaluation of medical technology will become increasingly acceptable as an integral part of the reimbursement processes of health plans. Our belief rests in the likelihood that rapidly rising health care costs along with the desire to improve quality will promote the use of explicit, objective methods for making difficult choices.

The authority for making coverage decisions under Medicare is defined under Section 1862 (a)(1)(A) of the Social Security Act, which requires that payment be made only for items or services that are "reasonable and necessary" for the diagnosis and treatment of illness or injury. Coverage decisions for new items and services under Medicare can be made either at the local level by Medicare's contractors or at the national level by HCFA. A small but growing number of decisions are now made at the national level, and interested parties can participate in the process. HCFA makes all documents available to the public, includes input from a public advisory committee, and makes its decisions under timelines specified in the public record.

The specific criteria for deciding whether an item or service is reasonable and necessary have yet to be established formally through the regulatory process. Still, the critical step in making such decisions is for HCFA to determine whether the item or service is medically effective, meaning that the benefits to the patient of the service exceed its risks.

To determine medical effectiveness of new technology, HCFA systematically collects and analyzes all data relevant to the intervention. A number of methodological issues are evaluated, including patient outcomes (clinical measures, morbidity, mortality, health-related quality of life, and functional status), adequacy of sample size, duration and completeness of patient follow-up, and study design. HCFA scrutinizes potential for bias when estimating the impact of the technology on patient outcomes. In general, HCFA uses a hierarchy of study designs for this purpose, with randomized studies and other controlled studies (e.g., case control, comparison group studies) having the least potential for bias. Uncontrolled case series, case reports, and informal consensus methods carry higher risk of biased results. HCFA carefully considers data from all study designs and evaluates their applicability to the specific coverage decision.

HCFA recognizes that it is in the interest of the Medicare program to selectively use its reimbursement authority to support research on clinical effectiveness. Recently, HCFA issued a national coverage policy to allow for the reimbursement of routine patient care costs in many high-quality clinical trials. In a limited number of cases (for example, lung volume reduction surgery and carotid angioplasty for stent placement), HCFA has allowed for the payment of an otherwise non-covered service under study within the protocol. Hopefully, efforts such as these—combined with careful review of the evidence for coverage decisions—will improve the quality of care and keep the Medicare program affordable.

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