Coverage of Laser Technology by Health Insurers

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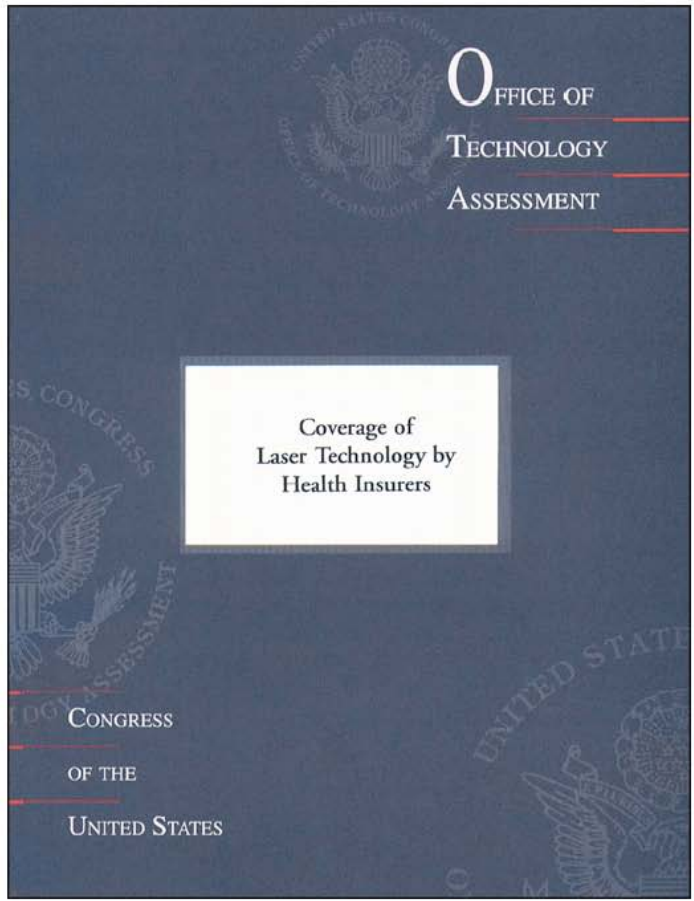

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Contents

Summary[1]

New medical technologies hold both the promise of significant health benefits and the prospect of additional health care spending. Private health insurance companies—through which most health care is paid for—shoulder a considerable responsibility in deciding which new technologies will be covered by insurance, and when in the cycle of development the time arrives to approve coverage. In general, insurance coverage is denied for technologies that are considered unproved or experimental. Despite the obvious importance of these decisions, relatively little systematic information is available about the procedures that insurers go through and the criteria they use to weigh the evidence.

This background paper presents some empirical information on how insurers consider payment for new medical devices. It describes the survey results of medical directors affiliated with private health insurers about their coverage decisions using, as examples, three applications of lasers: laser angioplasty for opening narrowed or blocked coronary arteries; laser discectomy for treating herniated intervertebral discs; and photodynamic therapy (using a light–sensitive dye) for bladder cancer.

Though there is no set procedure that all insurers follow to evaluate new technologies for coverage under their policies, it appears that most companies—whether indemnity insurers or health maintenance organizations (HMOs)—go about the process similarly. The company medical directors are nearly always involved in coverage decisions and, in most companies, are assisted by a committee.

The factors weighed in coverage decisions appear to be relatively consistent across companies. Among the most important are medical acceptability, efficacy, safety, cost–effectiveness, and regulatory considerations (in the case of lasers, Food and Drug Administration (FDA) approval of the device). One of the differences found between decisionmaking of indemnity insurers and HMOs was that HMOs appear to give more weight to cost–effectiveness—they were less likely to cover a new technology if it had a higher cost for the same effectiveness.

The largest barrier to decisionmaking, for all types of insurers, is the paucity of reliable information on the effectiveness, safety, and cost–effectiveness of new technologies at the time coverage decisions have to be made. Insurer medical directors view the medical profession, health care institutions, manufacturers, and the federal government as having the greatest responsibility for assuring that technologies yield reasonable benefits at reasonable costs.

[1] This background paper is based on "Technology Coverage Decisions: The Process and Considerations Used by Health Plans,," unpublished contractor report prepared by C.A. Steiner, N.R. Powe, and G.F. Anderson for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1995.

Coverage of Laser Technologies by Health Insurers

Advanced medical technologies are a hallmark of U.S. medicine: almost without exception, they come into use earlier and are used more widely than they are in other countries. From advanced imaging equipment to new surgical techniques, the United States leads all developed nations (31). These new technologies are often welcomed by the medical community and the public as the cutting edge in diagnosis and treatment and many important medical innovations are developed and used first in the United States. But advanced technology comes at a price, and may be responsible for as much as half the increase in health care spending over the last 20 years (18). Insurers have an important effect on the fate of new technologies by their decisions on which new technologies will be covered. This background paper reports the results of a survey of medical directors within private insurers concerning their decisionmaking process on covering new laser technologies in medicine.

DECIDING TO PAY FOR NEW TECHNOLOGIES

Physicians are clearly key to the introduction of new technologies; but a vital and increasingly active role is played by insurers of various kinds who must pay for the use of these new items on behalf of their customers. At some point, insurers must decide whether each new technology warrants coverage, be it a drug, device, or procedure. Relatively little is known about the process insurers use to make these decisions (5,9,11,30,35).

Private insurers have set up some formal technology assessment programs; but the number of evaluations they conduct is limited, and their conclusions are not always binding on the plans. For example, the Blue Cross and Blue Shield Association (BCBSA) (10) makes coverage recommendations based on a formalized process that includes a medical advisory panel. BCBSA considers a technology eligible for coverage if five criteria are met:

1. The technology must have final approval from a regulatory body (e.g., FDA);
2. There must be scientific evidence concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome (e.g., survival, quality of life, ability to function);
4. The technology must be as beneficial as technologies currently existing; and
5. Net improvements must be attainable outside the research setting.

The results of these assessments are provided to BCBSA member plans but plans are *not required* to follow recommendations and can perform their own assessments.

Though public insurers (Medicare and Medicaid, in particular) have a role in assessing new technologies for coverage, in the end it falls mainly to private insurers to make coverage decisions, for the following reasons. First, private carriers insure almost three-quarters of the insured U.S. population. Second, while the Health Care Financing Administration (HCFA, part of the Department of Health and Human Services) is responsible for administering the Medicare program, it issues only about 10 national decisions each year affecting the coverage of new technologies or procedures (33). And third, Medicare's claims and payment policies are administered by private contractors across the country (e.g., BCBS, Travelers Insurance Company, etc.) who make day-to-day decisions about the appropriateness of paying for items of medical care on behalf of Medicare.

The Changing Private Insurance Market

Two decades ago the insurance market consisted entirely of indemnity insurers (coverage that pays doctors, hospitals, and other providers for treatment given), but since that time managed care organizations, which combine health care delivery with the insurance function, have taken over a substantial and growing portion of the market. In 1992, an estimated 35 million members were enrolled in 558 HMOs, and 143 million people were covered by 1,200 or so private commercial insurers and 69 BCBS plans. Another 45 million are enrolled in preferred provider organizations (PPOs) and other forms of managed care organized by conventional indemnity insurers (14).

Different types of insurers may have different incentives for evaluating and deciding about covering new technologies, but almost nothing is known about how they differ. A better understanding of how this process occurs in different types of insurance organizations could be helpful in understanding the likely long-term impact of the growing managed care market on the way health care is delivered and how much it costs. The tightening financial climate in health care, with greater emphasis on price competition, is likely to make technology assessment and coverage an even more important function within the insurance industry.

THE COVERAGE DECISIONMAKING PROCESS

Though limited, some sources of information relating to the coverage decisionmaking process exist. A recent U.S. General Accounting Office (GAO) report on technology assessment and medical coverage decisions for Medicare (34) noted that only a few national coverage decisions for Medicare are made by HCFA while the remaining are regional decisions made by the 79 contractors that process claims under contract to HCFA. The Agency for Health Care Policy and Research assesses technologies at the request of HCFA and makes recommendations about coverage. The factors considered in coverage decisions include the potential expense to the Medicare program, the potential for widespread use in medical practice, the level of disagreement about the technology's safety and effectiveness, and the variation among contractor coverage decisions. The sources of information used to make these decisions include physicians, suppliers, manufacturing groups, and the contractors.

HCFA coverage decisions are made by Technology Advisory Committee. This 26-member committee, which meets for one and one-half days every quarter, is made up of HCFA physicians and other officials (about half the committee), contractor medical directors (seven), and officials from the National Institutes of Health, the Civilian Health and Medical Program of the Uniformed Services, the BCBS Association, FDA, and the Office of Health Technology Assessment. Coverage decisions can take from two months to several years to develop, depending on the issue's complexity. Once a decision is made, it is published as a proposed rule in the *Federal Register.* The resulting reviews and public comments are

incorporated into the final notice, which is published (34).

Most Medicare coverage decisions are made not through the process described above, but by the contractors who administer claims under Medicare. Lacking a national coverage decision, the 32 contractors review technologies themselves and make their own coverage decisions. This means that contractors may use no formal criteria, may develop their own criteria, or may use criteria developed by national insurers. Some create internal committees to perform technology assessments, although others have a more informal process. The only requirements are that each contractor has the equivalent of a full-time medical director responsible for making these decisions, and that representatives from the local provider community review all proposed medical policies. It is not surprising that Medicare coverage varies widely (34).

Less is known about the process of making coverage decisions in the private insurance community. A study of insurance coverage for patients in clinical trials of autologous bone marrow transplantation for breast cancer (19) concluded that, in that case, the decisionmaking process was arbitrary and capricious. Coverage for patients enrolled in these clinical research trials varied among third-party payers, appeared to bear little relation to available medical or scientific information, and varied from one request to another (similar patients and identical protocols). Some of the inconsistency in coverage may result from the influence of legal battles over coverage of this experimental intervention (1,13).

THE SURVEY

The aim of the survey, which was carried out under contract to OTA, was to find out how private insurance companies in the United States decide about the coverage of new medical technologies under their plans. Questions were asked to determine who is responsible for and involved in coverage decisions, the criteria used for deciding, the timing of decisions, and what information is used in the decisionmaking process. Three laser technologies were used as examples to illustrate specific considerations applied to making coverage decisions.

The Technologies

Three quite different laser technologies were the focus of this survey: laser angioplasty, laser discectomy, and laser photodynamic therapy for bladder cancer (box A). The three technologies are used by different medical specialties and have very different characteristics in terms of what is known of their effectiveness and safety. They were chosen specifically because they are at different stages of development and use. Laser angioplasty has been relatively well studied and reported on in the published medical literature. The use of lasers for percutaneous discectomy, though FDA approved, has not been well studied. There are only limited data available regarding its safety or effectiveness relative to the standard percutaneous discectomy and open-back surgery. Finally, laser photodynamic therapy for bladder cancer had not yet been submitted for FDA approval at the time of the survey.[2] Though still in its investigative stage, the survey portrayed this technology as offering additional benefits over other available treatments.

The Questionnaire

The questionnaire had three sections (see appendix B). The first section addressed coverage issues relating specifically to the three laser technologies. A short summary regarding the available data, FDA approval status, side effects, and how it compares with alternative therapies preceded

[2] As of June 1995, laser photodynamic therapy had not yet been approved by the FDA (8).

BOX A: Laser Applica

Laser angioplasty

When arteries of the heart become blocked or narrowed by the gradual accretion of plaque (a collection of abnormal fat, cells, and debris), not enough blood gets to the heart and angina (chest pains) or eventually, a heart attack may result. One treatment for this atherosclerosis is angioplasty an intervention to open blocked or narrowed arteries. To get to the target artery, a needle is inserted (after local anesthesia) into the appropriate blood vessel. A catheter is then introduced and advanced to the narrowed area using a visualization technique (fluoroscope). Once the device is in place, angioplasty can be performed. The first method reported used catheters of increasing size to open the obstruction (23). Now many different methods are available. With balloon angioplasty a catheter with a collapsed balloon is used. Once in place the balloon is opened and the plaque is compressed against the sides of the artery resulting in a larger passageway, or lumen. Instead of compressing the plaque, it can be removed by laser energy. In this case a special catheter tip is inserted and laser energy IS transmitted to the narrowed artery, destroying the plaque. The laser technique had been fairly well studied at the time of the survey, and the published literature provided relatively good information about its safety effectiveness, and cost. Laser angioplasty may have a higher complication rate, be somewhat less effective, and be more expensive than balloon angioplasty (6,7,1 6,24).

Laser discectomy

Lower back pain was first linked with herniated lumbar intervertebral discs in 1934. Now it is one of common conditions treated by neurosurgeons in the United States (23). The intervertebral disc is made up of a tough *annulus fibrosis* surrounding a gelatinous material, the *nucleus pulposus,* which becomes more fibrous with age. An injury to the back can weaken the surrounding annulus, and with this, the nucleus pulposus can protrude (herniate) outside the ring. The disc is immediately behind the spinal cord so herniation may compress the nerve roots, causing back pain, and tingling or weakness of the legs. The surgical options to relieve cord compression are open back surgery and percutaneous methods, both mechanical and laser. Open surgery requires general anesthesia and entails an incision and dissection of the area, then removal of the disc. Several days of hospitalization are required. With the percutaneous methods, local anesthesia can be used while a needle is inserted into the affected region and the disc removed by suction or laser energy. The patient can go home the same day. There is relatively little reformation on the safety or effectiveness of laser discectomy compared with the alternatives (15,21 ,25). The laser used for this technique does, however, have Food and Drug Administration (FDA) approval.

Photodynamic therapy

Photodynamic therapy for bladder cancer was in an investigational stage (not yet FDA approved) at the time of the survey (and still IS considered investigational in 1995). The treatment involves injecting the patient with a photosensitive substance that is taken up selectively by the cancer cells. The area of the tumor is then irradiated with a laser of the appropriate wavelength to “excite” the photosensitizing agent, releasing highly active *singlet oxygen* (i.e., single atoms of unbound oxygen), which destroys the malignant tissue around it. The description of this technology on the survey questionnaire portrayed it as being supported by ample evidence for its effectiveness in bladder tumors for which conventional treatment had failed. In addition, few complications had been reported (7,17,26,27,28).

SOURCE: Office of Technology Assessment, 1995, based on reference 29

TABLE 1: Factors Possibly Influencing Coverage Decisions (listed as choices on questionnaire)

- Medically acceptable, reasonable, or necessary
- Experimental or investigational technique
- Potential for increased cost of the procedure due to laser technique
- Potential for decreased cost of the procedure due to laser technique
- Potential for increased volume of this procedure due to new laser technique
- Potential for decreased volume of this procedure due to new laser technique
- Concern that coverage will prompt influx of new patients into insurance plan
- Benefits policy excludes procedure
- Denial of coverage maybe legally challenged in the court system
- Alternate technique available which is clinically proven effective
- Increased complication rate
- Decreased complication rate
- Increased efficacy of this technique
- Decreased efficacy of this technique
- Potential differences between clinical trials (efficacy) and community experience (effectiveness)
- FDA approval
- Increased cost-effectiveness
- Decreased cost-effectiveness
- Complications present a liability risk for the company
- Technique is outpatient rather than inpatient
- Technique is inpatient rather than outpatient
- Laser technique is potentially last resort
- What other carriers currently cover
- Other

[a]The treatment is generally accepted by the professional medical community as an effective and proven therapy and is appropriate for the treatment of sickness or injury.

SOURCE: Office of Technology Assessment, 1995, based on reference 29.

exploration of the factors that would be considered in a coverage decision. For each technology, the respondents were asked to choose from among a list of considerations (table 1) the five that would weigh most heavily *in favor* of covering the technology, and the five that would weigh most heavily *against* it. The first section ended by asking whether the insurer was providing coverage for each of 15 laser procedures (figure 1) to assess actual coverage of these technologies.

The second section of the questionnaire queried the general medical coverage decisionmaking process. Questions were asked to find out who was usually involved in coverage decisions, what types of information would be used, the timing of the decisions, what circumstances tended to make decisionmaking more difficult, as well as questions soliciting the respondents' opinions on various coverage matters.

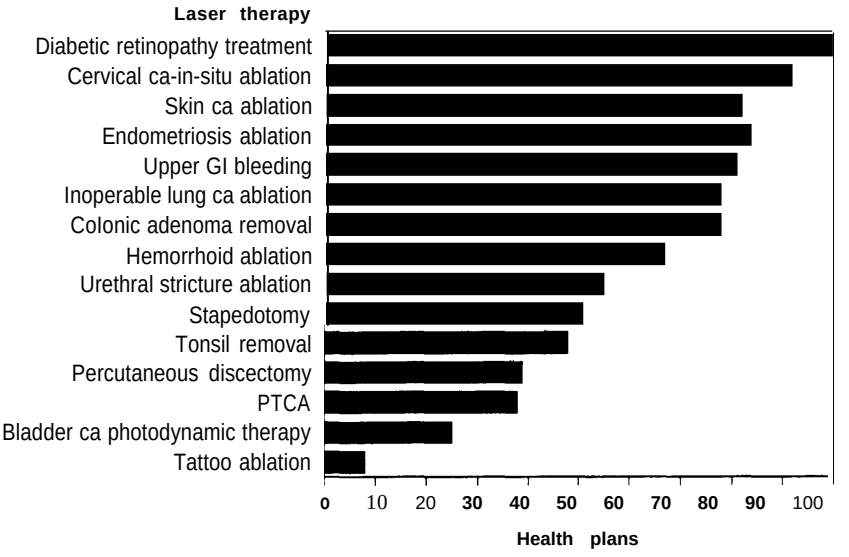
The third section asked standard questions about the characteristics of the company and about the person filling out the survey (in most cases, the company's medical director).

Companies Surveyed

The intent was to survey virtually all private health insurers in the country. Questionnaires were sent to all members of three trade associations—the Health Insurance Association of America, Group Health Association of America, and Blue Cross/Blue Shield—and to the four largest commercial plans in the country (Aetna, Cigna, Metropolitan Life, and Travelers), which were not members of a trade association. In total, 573 questionnaires were mailed. Between October 1993 and March 1994, three copies of the questionnaire were sent, as well as two postcard reminders, to try to assure a good response rate.

Overall, 41 percent of the questionnaires were completed and returned (table 2). All four large commercial companies responded and, in general, the larger HMOs and other indemnity insurers also responded (figure 2), so the response represented approximately 70 percent of all people with private health insurance in the United States, though less than half the companies. The respondent companies (other than being larger than average) were generally representative of the insurance market in their basic characteristics. The characteristics of the responding plans are shown in table 3.

FIGURE 1: Health Plans Coverage of Different Laser Therapies



Abbreviations: ca=carcinoma: GI=gastrointestinal; PTCA=percutaneous transluminal coronary angioplasty

SOURCE: Office of Technology Assessment, 1995; based on reference 29

Survey Results

On the question of who is involved with coverage decisionmaking, it is clear that medical directors play a central role. About 80 percent of the questionnaires were filled out by medical directors, and nearly all the respondents indicated that the medical director had major involvement in these decisions.

Respondents believed that insurers should continue to play a role in assuring that new technologies yield reasonable benefits at a reasonable cost, but that physicians, health care institutions, manufacturers, and the federal government should shoulder more of that responsibility (figure 3).

Coverage of Laser Therapies

There was considerable variation in coverage of laser technologies. Less than 40 percent of the responding companies were covering laser angioplasty or laser discectomy, and about 25 percent were covering photodynamic therapy for bladder cancer at the time they answered the survey. Among the list of 15 laser technologies, only tattoo ablation was covered less frequently than the three focused on in the survey. The only technology covered by all the companies was laser treatment for diabetic retinopathy (figure 1).

Decisionmaking About the Three Sample Technologies

Overall, the factors chosen most often among the top five that would weigh *in favor of coverage* for any of the three technologies are:

1. Medically acceptable, reasonable, and necessary;
2. Increased efficacy of the technique;
3. Increased cost-effectiveness;
4. FDA approval; and
5. Decreased complication rate.

There was more variation regarding the factors that would weigh *against coverage* among the three technologies. The factors most often noted included:

1. Experimental nature of the technology,
2. Increased complication rate,
3. Alternate technique available which is effective,
4. Decreased efficacy of the technique,

TABLE 2: Final Response Rate

Types of plans	Respondents (n)	Total mailings (n)	Response rate (o/o)
HIAA member plans	39	104	37.5%
BCBS member plans	73	140	52.1
GHAA member plans	115	315	36.5
Large indemnity plans[a]	4	4	100.0
All clans	231	563	41.0

[a]Aetna, Cigna, Metropolitan-Life, and Travelers.

KEY: BCBS = Blue Cross and Blue Shield; GHAA = Group Health Association of America, Inc.; HIAA = Health Insurance Association of America

SOURCE: Office of Technology Assessment, 1995

5. Decreased cost-effectiveness of the technique, and
6. Benefits policy excludes the technique.

Laser photodynamic therapy was not FDA approved and this factor was ranked in the top five for recommendations against coverage. (Thirty-seven percent of respondents ranked this in the top five for photodynamic therapy, as opposed to 8 percent for both laser angioplasty and discectomy.)

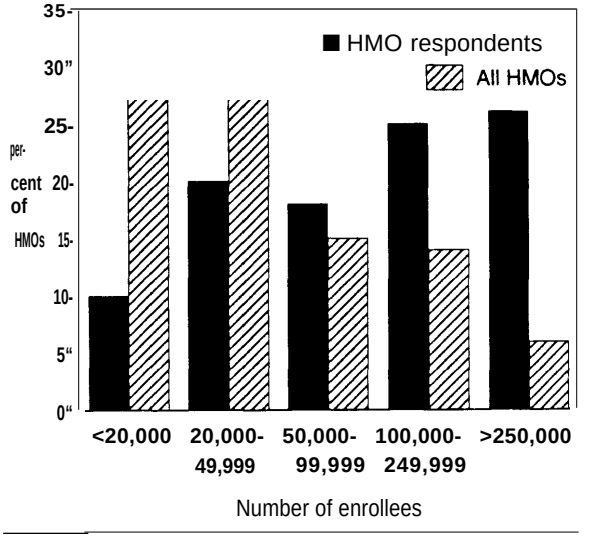
Differences Among Plan Types

Respondents from HMOs were more likely than those from indemnity plans to list the potential for decreased costs as a point in favor of covering laser angioplasty and laser discectomy. There were also differences between HMO and indemnity plans in what they considered important considerations against covering a technology. For laser angioplasty and discectomy, HMOs were more likely than indemnity plans to list "increased complications rate" as an important factor. For photodynamic therapy, indemnity plans were more likely than HMOs to list "potential increased volume due to laser technique." For this technology, HMOs were more likely to list "complications may present liability risk" than were indemnity plans.

Awareness of Use of Laser Technology

Insurers must be aware that they are being asked to pay for a new technology before they can decide to make a formal coverage decision about it. Insurance claims are generally made using billing codes that represent certain procedures. Until a new technology is given a specific code, physicians often use an existing code, so the insurer will not necessarily be aware that the new technology was used (e.g., laser angioplasty might be billed using the general code for "angioplasty, single

FIGURE 2: HMO Respondents and Entire Industry by Number of Enrollees[a,b]



Abbreviations: HMO=health maintenance organization

[a]Total HMO respondents = 159. Twelve did not report size of plan

[b]n = 552 for all HMOs

SOURCE: Group Health Association of America, Inc., *HMO Industry Profile, 1993 Edition* (Washington, DC 1993), Off Ice of Technology Assessment, 1995, based on reference 29

TABLE 3: Characteristics of All Respondents

Characteristic	Number (n=231)	Percent
Company type		
• HMO	159	69%
• indemnity	72	31
Size[a]		
• small	106	49.5
• large	108	50.5
Profit status[b]		
• for profit	121	54
• not-for–profit	103	46

[a] Size of company in terms of enrollees for HMOs and covered lives for indemnity carriers. Six size ranges taken from questionnaires and combined into two groups. Seventeen respondents did not report size.
[b] Seven respondents did not report profit status

KEY: HMO = health maintenance organization.

SOURCE: Office of Technology Assessment, 1995; based on reference 29.

vessel"). None of the three laser technologies focused on had its own billing code at the time of the survey. A series of questions was asked on this issue.

For each technology, 64 to 78 percent of respondents said they would not have known that the laser procedure had been used based on billing information. In all three cases, indemnity insurers were less likely to be aware of the new technology than were HMOs.

Respondents were asked how they were likely to find out that a new procedure was being used. Most commonly, they were alerted by a query from a practitioner, by higher than average charges for treatment, or by utilization review. Internal discussion with medical or insurance colleagues was a more frequent source of awareness for HMOs than for indemnity insurers. Indemnity insurers were more likely to rely on manufacturers to alert them to a new laser technology.

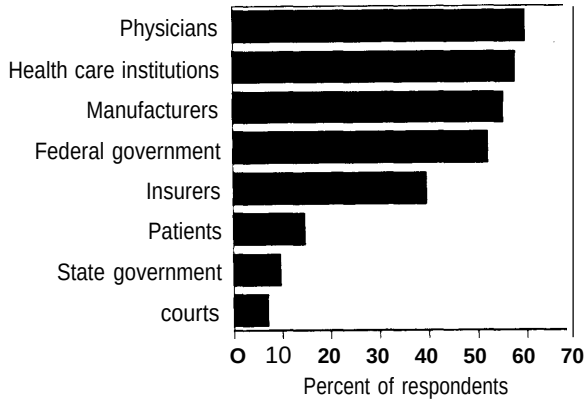
Once aware of the use of laser angioplasty in the plan, factors (cited more than 60 percent of the time) that would prompt a specific medical coverage policy decision for this technology are: 1) concern that this is an experimental procedure, 2) covering a technique with more potential complications, and 3) the technique is not considered a community standard.

Medical Director Characteristics and Role in Coverage Decisionmaking

Ninety-three percent of all medical directors held a medical degree, with an additional 3 percent holding another medically-related degree. Most were from primary care disciplines (79 percent). The most frequent secondary degrees were Master of Business Administration (32 percent) and Master of Public Health (25 percent). The makeup of the committees that assisted medical directors varied. Half of the respondents noted the inclusion of their "staff' and of community physicians on the committee. About one-third of the committees included attorneys and representatives from utilization review, benefits, and claims departments.

Ninety-two percent of the respondents noted that the medical director is involved with the review process for a medical coverage decision. The responsibility for making a medical policy coverage decision was either that of the medical director alone (27 percent) or the committee (68 percent). Three-quarters of the respondents indicated that,

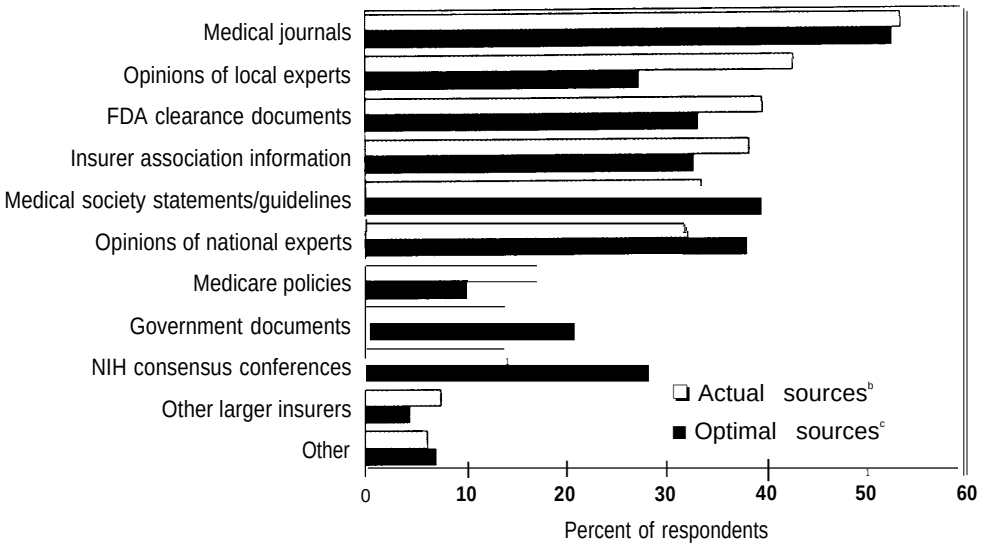
FIGURE 3: Respondents' Attitudes About Who Bears Greatest Responsibility for Assuring Technologies Yield Reasonable Benefits at Reasonable Costs[a]



[a] Percent of respondents who indicated which party should have a great deal of responsibility

SOURCE: Office of Technology Assessment, 1995: based on reference 29.

FIGURE 4: Actual and Optimal Sources of Information[a,b]



Abbreviations: FDA=U.S. Food and Drug Administration; NIH=National Institutes of Health.

[a] Medical directors were asked to rank actual and optimal sources of information used when making a medical coverage decision.

[b] Four respondents did not report actual sources. Two respondents did not report optimal sources.

SOURCE: Office of Technology Assessment, 1995, based on reference 29.

ideally, a committee should make this decision. Indemnity insurers were more likely than HMOs to believe that ultimate responsibility for coverage decisions should lie with the medical director alone.

The timing of the decision varied with the type of plan. Retrospective decisions are coverage decisions made after the medical service is rendered. This is in contrast to prospective decisions, when approval for medical services is made before it is provided. Retrospective decisionmaking was noted a quarter of the time for HMOs as compared to just over half the time for indemnity plans. Both types of plans reported that optimally, decisionmaking should be prospective (98 percent and 89 percent of HMO and indemnity respondents, respectively).

Sources and Types of Information Used for Coverage Decisions

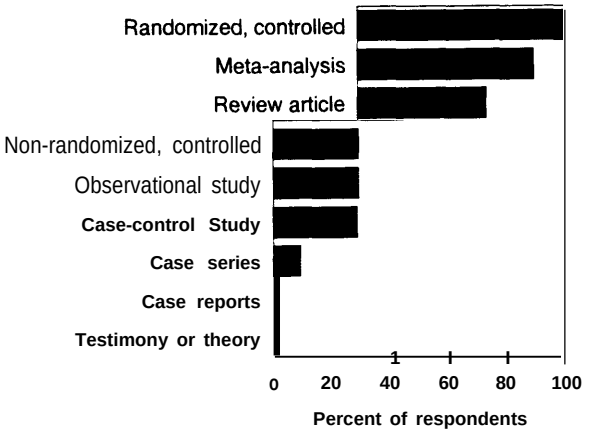
A variety of questions was asked about the sources and types of information used by insurers for making coverage decisions about new technologies. Medical journals, the opinions of local experts, and FDA clearance documents were the most frequently cited information sources. But they also indicated that they thought the opinions of local experts *should* be used less and that formal national committee statements, such as NIH consensus conferences, *should* be used more (figure 4).

A variety of research types were considered useful for decisionmaking. The top three ranked types of evidence are: randomized controlled trials, meta-analyses, and review articles (figure 5).

Cost-Effectiveness as a Consideration in Coverage Decisions

The survey asked whether plans would be likely to cover new technologies with varying ratios of cost to effectiveness. The responses indicated that higher cost technologies are less likely to be covered than alternative technologies, without some benefit in effectiveness (figure 6). However, indemnity insurers were more likely than HMOs to

FIGURE 5: Hierarchy for Types of Evidence[a,b]



[a]Medical directors were asked to rank top three choices for types of evidence used when reviewing a laser therapy.
[b]Type listed in any rank order. Six respondents did not rank types of evidence.

SOURCE: Office of Technology Assessment, 1995; based on reference 29.

cover a new technology that is equal in effectiveness to an existing one, even if it is more expensive.

Barriers to Making Coverage Decisions

Respondents indicated that the most significant barriers for them in making coverage decisions concern lack of timely data: effectiveness data, cost-effectiveness data, and safety data. Administrative, regulatory, and legal barriers were second-W (figure 7). Indemnity plans also noted health care provider disagreement with insurer coverage decisions ("provider contention") as a significant barrier.

CONCLUSIONS

Health insurers (both indemnity insurers and managed care organizations) play an important role in the introduction and dissemination of new medical technologies. Their decisions on covering new technologies affect both the cost and quality of health care for the country, yet little is known about the processes or the criteria used to make these decisions. This survey elucidated some aspects of the process, primarily focusing on applications of medical devices.

This survey focused on only one level of the coverage decision process. It did not explore decisions handled at other levels, such as the claims department, or at what point a coverage issue is addressed by a formal decision. Once a decision regarding medical coverage is necessary, the insurance company medical directors are most often involved. Usually, a committee advises the medical director on specific coverage questions, but in some companies, the responsibility rests solely on that individual. All the readily available sources of information may be used in making coverage decisions, from the results of randomized controlled trials to the opinions of local experts.

Even though there is no standardized procedure that all insurers follow in making coverage decisions, the factors that weighed most heavily in the decisions were quite similar across companies. The medical acceptability of and need for the new technique, whether devices involved had been approved by FDA, the cost-effectiveness of the new technology compared with existing treatments, the complication rate, and where the technology was along its path of development (e.g., still experimental versus accepted practice) were among

FIGURE 6: Cost and Effectiveness in Medical Coverage Decisions[a]

	Relative effectiveness (in percent)		
Relative cost	Greater effect	Equal effect	Less effect
Greater cost	90	24	3
Equal cost	99	95	4
Less cost	98	99	14

[a]Figure shows percentage of respondents who would cover a new technology given a cost and effectiveness profile relative to a standard technology.

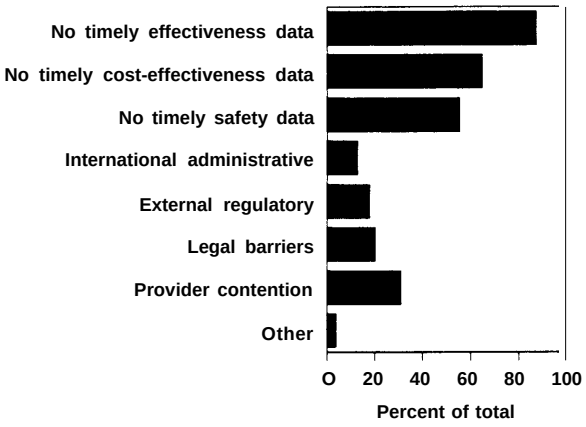
SOURCE: Office of Technology Assessment, 1995, based on reference 29.

the most important considerations. Many coverage determinations are made retrospectively—i.e., when the company is billed after the procedure has been carried out, and this fact could also weigh in whether it will be paid for. (Retrospective evaluation is more often the case for indemnity insurers than for HMOs where a larger percentage of evaluations is carried out prospectively, before the service has been given.) Most insurers prefer a prospective decisionmaking process.

Coverage decisions are often difficult for insurers because reliable information on effectiveness, cost-effectiveness, and safety often is not adequate when decisions have to be made. Cost-effectiveness is given considerable weight in these decisions, although indemnity insurers appear to be somewhat less concerned about it than are HMOs

Private insurers recognize that they will continue to be gatekeepers for many new technologies, and in that role they can be most effective if armed with better information about the technologies at the earliest possible time. The decisionmakers in these companies also, however, would appear to welcome greater responsibility on the part of the medical profession, health care institutions, manufacturers, and the federal government in assuring that new medical technologies are effective, safe, and relatively cost-effective before they diffuse into widespread use.

FIGURE 7: Barriers to Establishing Medical Policy Optimally[a,b]



[a] Respondents were asked to rank barriers in any order.
[b] Seven respondents did not report barriers.

SOURCE: Office of Technology Assessment, 1995, based on reference 29.

Appendix A: Overview of OTA Assessment: Technology, Insurance, and the Health Care System

A

Background

Congress has been concerned for many years with serious and growing problems of health care costs, access, and quality. In response to a request from the Senate Committee on Labor and Human Resources (Edward Kennedy, then Chairman) that was endorsed by the House Committee on Energy and Commerce (John Dingell, then Chairman), the House Committee on Ways and Means Subcommittee on Health (Bill Gradison, then Ranking Minority Member), and Senator Charles E. Grassley (Committees on Budget, Finance, Special Committee on Aging), the Office of Technology Assessment's (OTA) assessment, Technology, Insurance, and the Health Care System addresses these congressional concerns by focusing on the following issues:

1. What does the available literature say about the impact of health insurance on access to care and patient health outcomes?
2. Can a minimum benefit package for uninsured people be fashioned from the perspective of effectiveness and cost-effectiveness?

In addition, Senator Ted Stevens (as a member of the Technology Assessment Board) asked OTA to examine an additional question under the auspices of this assessment:

3. What cost implications do the leading types of health care reform proposals have in seven areas: health care spending and savings; Federal, State, and local budgets; employers (large and small); employment; households (low-, middle-, and upper-income); other costs in the economy; and administrative costs?

The assessment was approved by the Technology Assessment Board in April 1991, and began in July 1991. In June 1992, the letter was received from Senator Stevens. An advisory panel for the overall assessment was formed in November 1991. The advisory panel met in January 1992, December 1992, and in May 1993.

Documents Produced as Part of the Assessment

The following documents have been or will be available as part of the assessment.

PUBLICATIONS AVAILABLE FROM THE U.S. GOVERNMENT PRINTING OFFICE

Does Health Insurance Make a Difference? September 1992.

This interim report, requested by the U.S. Senate Labor and Human Resources Committee, summarizes the state of the literature on the rela-

tionships among insurance coverage, access, and patient health outcomes; provides a conceptual framework for evaluating access to health care and the health effects of such access; and provides an overview of insured and uninsured populations in the United States as of 1990. The background paper is available from the U.S. Superintendent of Documents (GPO stock number 052-003-01301-1, $5.00 per copy).

An Inconsistent Picture: A Compilation of Analyses of the Economic Impacts of Competing Approaches to Health Care Reform by Experts and Stakeholders, June 1993.

This report compiles and summarizes available analyses of the economic impacts of four major competing approaches to health care reform (popularly known as "single payer," "play or pay," "individual tax credits or vouchers," and "managed competition"). The report was requested by Senator Ted Stevens, and was released in June 1993. The report is available from the U.S. Superintendent of Documents (GPO stock number 052-003-01327-4, $8.00 per copy).

Benefit Design Series—Publications from this series of reports explore issues involved in designing a benefit package based on effectiveness and cost effectiveness, in relation to other critical factors in benefit design. Two of the topics (clinical preventive services; mental health/substance abuse) were chosen in part because of Congressional interest in them as contentious, "gray" areas in benefit design and in part because of OTA's already-existing expertise in the topics. Patient cost-sharing was in some respects a new area for OTA, but was an issue of particular importance in the benefit design debates. The general issues report will pull together lessons learned about benefit design from the other reports in the Benefit Design Series and from other sources, including previous work by OTA. The reports in this series are:

Benefit Design in Health Care Reform: Clinical Preventive Services, September 1993.

This report addresses issues pertaining to insurance coverage of clinical preventive services. The report describes how information on effectiveness and cost-effectiveness can, and cannot, be used for purposes of insurance benefit design and for improving access to effective clinical preventive services. This report is available from the U.S. Superintendent of Documents (GPO stock number 052-003-01340-1, $7.50 per copy).

Benefit Design in Health Care Reform: Background Paper—Patient Cost-Sharing, September 1993.

This background paper describes what is known, and not known, about the effects of patient cost-sharing on the use of health care services, expenditures, and health outcomes based on a review of the literature. This background paper is available from the U.S. Superintendent of Documents (GPO stock number 052-003-01339-8, $4.50 per copy).

BACKGROUND PAPERS AVAILABLE ONLY FROM OTA

These background papers are available from OTA. For congressional use call 202/224-9241, and for public use, call 202/228-6590.

Health Insurance: The Hawaii Experience—Background Paper, June 1993.

This background paper provides a detailed look at the State that is often considered a model for what other States can do to help provide universal or near-universal health insurance coverage for their residents. Unfortunately, valid data were not available to demonstrate either the overall financial costs of Hawaii's approach or the health effects on residents.

Coverage of Preventive Services: Provisions of Selected Current Health Care Reform Proposals, October 1992.

This background paper summarizes the provisions of selected congressional (102d Congress) and private health care reform proposals with respect to the coverage of clinical preventive services.

Contractor Papers Available from National Technical Information Service, Congressional Research Service, or from the Authors

Primary Care for the Uninsured: A Review of the Literature, Congressional Research Service, May 1993.

Paper prepared under contract to OTA by David Blumenthal, M.D., M.P.P., Elizabeth Mort, M.D., M.P.H., and Jennifer N. Edwards, M.H.S., Health Policy Research and Development Unit, General Internal Medicine, Massachusetts General Hospital.

The Relationship Among Insurance Coverage, Access to Services and Health Outcomes: Case Study of Depression, July 1993.

Paper prepared under contract to OTA by Thomas McGuire, Ph.D., Department of Economics, Boston University, Boston, MA.

Universal Health Insurance and Uninsured People: Effects on Use and Cost, August 1994.

Paper prepared under contract to OTA and CRS, by Steven Long and M. Susan Marquis, RAND Corporation, Washington, DC.

Appendix B: Survey on Medical Coverage Decisions for Lasers

B

Note: Survey should not be used, cited, quoted, or reproduced without the permission of the Johns Hopkins Medical Institutions.

QUESTIONNAIRE ON MEDICAL POLICY

SECTION 1: MEDICAL POLICY

Three laser applications that are currently available in different fields of medicine are described on the following pages. Each application is followed by a series of identical questions. The data presented in these descriptions are as clinically accurate as possible. We would like you to read each description and answer the questions based on the information provided in each case. This section requires the most reflection; Sections II and III require less time.

All responses will be kept strictly confidential.

I have previously completed this survey. _
(Please return in pre-addressed envelope.)

I am unable to complete the survey at this time.
(Please provide reason, if possible, and return in pre-addressed envelope.)

Would you like to receive a summary of results of this survey? —Yes —No

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2

Application I (Cardiovascular)

Percutaneous transluminal coronary angioplasty is performed in selected patients (approximately 16/1 0,000 persons >=35 years of age per year). Laser angioplasty is a more recent non-invasive technique for treating coronary obstructions. According to the medical literature, a significant obstacle to laser angioplasty is the inadequate diameter of recanalization achieved, such that there continues to be a need for subsequent balloon angioplasty in at least 70% of cases. Major complications, such as death, myocardial infarction and need for coronary artery bypass grafting, may be similar to the more conventional balloon angioplasty. However, complications such as dissection of the vessel can be substantially higher (up to 17%), and perforation of the vessel wall moderately higher(2.5%) when compared to conventional angioplasty. In addition, restenosis rates using laser assisted-angioplasty are similar to conventional balloon angioplasty. Therefore, laser angioplasty appears to increase complications, to be less effective than balloon angioplasty alone, and to add an increased expense to PTCA. Currently, this laser technique has no unique CPT code and would therefore be billed under the general code, 72982 Percutaneous transluminal coronary angioplasty; single vessel.

QUESTIONS

Q-1 **If the health care provider balls for this laser technique using the general CPT procedure code that is routinely paid, would you know that this laser application is being used? (Check one below)**

— *(1) Definitely not* — *(2) Probably not* — *(3) Probably yes* — *(4) Definitely Yes* 7

Q-2 **Which of the following would be most likely to alert you to use of this laser application on your insured population by a health care provider? (Please *rank* top three sources from the list provided below)**

01 Higher than average charge submitted by provider	07 Internet technology coverage committee
02 Provider queries about coverage policy	OS medical or trade publications
03 Patient queries about coverage policy	09 General public media
04 Manufacturers queries about coverage policy	10 Manufacturers advertising
05 Internally aware because our type of HMO initially approves the purchase of the laser	11 Informal discussions with your medical or insurance colleagues
06 Utilization review by medical record audit	12 Other _____

First likely source *(enter number)* _____ .9,9
Second likely source *(enter number)* _____ 10,11
Third likely source *(enter number)* _____ 12.13

Q-3 **Once you are aware that this laser is being used, which of the following factors would prompt YOU to make a specific medical coverage policy decision for this laser technique versus simply covering the routine procedure? (Please rank top three factors from the list provided below)**

1 High potential number of insured population affected	5 Concern over covering a technique with more potential complications
2 High potential cost	6 Concern that coverage may represent a liability risk
3 Concern that this is an experimental procedure	7 Other _____
4 Technique is not considered a commu nity standard	

First important factor *(enter numbed* — 14
Second important factor *(enter number)* — 15
Third important factor *(enter number)* — 16

Q-4 **For this laser technology as described, how strongly would each of the following considerations influence your company's decision to recommend coverage or deny coverage?**
(Please rank separately the top five considerations in favor of, and against, recommending coverage)

01 Medically acceptable, reasonable and necessary	12 Decreased complication rate
02 Experimental or investigational technique	13 Increased efficacy of this technique
03 Potential for increased cost of the procedure due to laser technique	14 Decreased efficacy of this technique
04 Potential for decreased cost of the procedure due to laser technique	Is potential differences between clinical trials (efficacy) and community experience (effectiveness)
05 Potential for increased volume of this procedure due to new laser technigue	16 FDA l pproval
06 Potential for decreased volume of this procedure due to new laser technique	17 Increased cost-effectivess
07 Concern that coverage will prompt influx of new patients into insurance plan	18 Decreased cost-effectivess
08 Benefits policy excludes procedure	19 Complications present a liability risk for the company
09 Denial of coverage may be legally challenged in the court system	20 Technique is outpatient rather than inpatient
10 Alternate technique available which is clinically proven effective	21 Technique is inpatient rather than outpatient
11 Increased complication rate	22 Laser technique is potentially last resort
The treatmnt is generally accepted by the professional therapy and is appropriate for the treatment of sickness or injury.	23 What other carriers currently cover
	24 Other medical community as an effective and proven

Most important consideration in favor of coverage	*(enter number)*	17,18
Second important consideration in favor of coverage	*(enter number)* _____	19,20
Third important consideration in favor of coverage	*(enter number)* _____	21.22
Fourth important consideration in favor of coverage	*(enter number)* _____	23,24
Fifth important consideration in favor of coverage	*(enter number)* _____	26.26

Most important consideration against coverage	*(enter number)* _____	27.28
Second important consideration against coverage	*(enter number)* _____	29,30
Third important consideration against coverage	*(enter number)* _____	31.32
Fourth important consideration against coverage	*(enter number)* _____	33,34
Fifth important consideration against coverage	*(enter number)* _____	35,36

From the list provided above, please record the two considerations that would be of least importance in favor of and against recommending coverage.

Least important considerations in favor of coverage	*(enter number)* _____	37.38
	(enter number) _____	39.40
Least important considerations against coverage	*(enter number)* _____	41,42
	(enter number) _____	43,4

4

Application II (Orthopedic and Neurosurgery)

Mechanical low back pain is a common and substantial health problem, which is treated though a variety of conservative and surgical interventions. Excision or destruction of the intervertebral disk is a therapy for selected patients with a herniated disk, (approximately 17 cases/ 10,000 persons >= 18 years of age per year) typically involving an open procedure on the spine, general anesthesia and a hospital stay. Percutaneous diskectomy was introduced in 1975, with a success rate for the percutaneous approach itself reported at 60-70 %, compared to 80-90% for the conventional surgery. The use of a Ho:Yag or Nd:Yag laser was more recently introduced as a technique for the ablation of the diseased disk. The procedure uses a fiber optic lens and laser, which are introduced percutaneously to a patient given local anesthesia, and sent home the same day. Although the laser is FDA approved, there is scarce clinical data on humans as to the laser's clinical safety, effectiveness and broad applicability for percutaneous diskectomy. Currently, this laser technique has no unique CPT code and would be billed under the general code, 62287 Aspiration Procedure Percutaneous, of nucleus pulposus of intervertebral disk, any method, single or multiple levels, lumbar.

Q-1 **If the health care provider bills for this laser technique using the general CPT procedure code that is routinely paid, would you know that this laser application is being used? (Check one below)**

— (1) Definitely not — (2) Probably not — (3) Probably yes — (4) Definitely Yes 45

Q-2 **For this laser technology as described, how strongly would each of the following considerations influence your company's decision to recommend coverage or deny coverage?**
(Please rank separately the top five considerations in favor of, and against, recommending coverage)

01 Medically acceptable, reasonable and necessary	12 Decreased complication rate
02 Experimental or investigational technique	13 Increased efficacy of this technique
03 Potential for increased cost of the procedure due to laser technique	14 Decreased efficacy of this technique
04 Potential for decreased cost of the procedure due to laser technique	15 Potential differences between clinical trials (efficacy) and community experience (effectiveness)
05 Potential for increased volume of this procedure due to new laser technique	16 FDA approval
	17 Increased cost-effectiveness
06 Potential for decreased volume of this procedure due to new laser technique	18 Decreased cost-effectiveness
07 Concern that coverage will prompt inflow of new patients into insurance plan	19 Complications present a liability risk for the company
08 Benefits policy excludes procedure	20 Technique is outpatient rather than inpatient
09 Denial of coverage may be legally challenged in the court system	21 Technique is inpatient rather than outpatient
	22 Laser technique is potentially last resort
10 Alternate technique available which is clinically proven effective	23 What other carriers are covering
11 Increased complication rate	24 Other

Most important consideration in favor of coverage	*(enter number)* __ __	46,47
Second important consideration in favor of coverage	*(enter number)* _____	48,49
Third important consideration in favor of coverage	*(enter number)* _____	50,51
Fourth important consideration in favor of coverage	*(enter number)* _____	52,53
Fifth important consideration in favor of coverage	*(enter number)* _____	54,55
Most important consideration against coverage	*(enter number)* _____	56,57
Second important consideration against coverage	*(enter number)* _____	58,59
Third important consideration against coverage	*(enter number)* _____	60,61
Fourth important consideration against coverage	*(enter number)* _____	62,63
Fifth important consideration against coverage	*(enter number)* _____	64,65

From the list provided above, please record the two considerations that would be of least importance in favor of and against recommending coverage.

Least important considerations in favor of coverage	*(enter number)* _____	66.67
	(enter number) _____	68,69
Least important considerations against coverage	*(enter number)* _____	70,71
	(enter number) _____	72,73

Application III (Oncology) 5

Photodynamic therapy is an experimental cancer therapy which is being studied for its effectiveness in transitional ceil carcinoma of the bladder. This therapy is currently undergoing evaluation for formal FDA approval for this cancer, but is not approved to date. For some stages of this tumor, no alternative, curative therapy exists. The therapy involves injecting a photosensitizing agent, usually a porphyrin-based compound into the patient, which is selectively taken up by the malignant tissue. The tumor is then exposed to a non-thermal appropriate wavelength of laser light from a tunable-dye laser. The molecule of the photosensitizing agent is excited, releasing a cytotoxic singlet oxygen species, which destroys the malignant tissue. Current literature suggests that photodynamic therapy is an important therapeutic intervention for refractor carcinoma-in-situ and prophylaxis of recurrent superficial transitional-cell carcinoma of the bladder. The reported complete response rates for carcinoma-in-situ to photodynamic therapy have consistently been 80-100%. There is also data to support prophylaxis through a single photodynamic session for recurrent cancers which have failed previous interventions, providing 12 to 20 months of disease-free intervals. No deaths have been reported due to photodynamic therapy. Complications include permanent bladder contracture which was reported in 10% of earlier patients. Patients also experience temporary urinary frequency, urgency and nocturia of variable severity. The photosensitizing agent is relatively non-toxic, except the patient must avoid sunlight and bright indoor lighting for a period of time. Therefore, although not yet FDA approved, photodynamic laser therapy for bladder cancer appears to have no significant complications, has unclear cost implications, but has increased efficacy over more conventional therapies.

Q-1 If the health care provider bills for this laser technique using the general CPT procedure code that is routinely paid, would you know that this laser application is being used? (Check one below)

— (1) *Definitely not* — (2) *Probably not* — (3) *Probably yes* — (4) *Definitely yes* 74

Q-2 For this laser technology as described, how strongly would each of the following considerations influence your company's decision to recommend coverage or deny coverage? (Please rank separately the top five considerations in favor of, and against, recommending coverage)

01 Medically acceptable, reasonable and necessary	12 Decreased complication rate
02 Experimental or investigational technique	13 Increased efficacy of this technique
03 Potential for increased cost of the procedure due to laser technique	14 Decreased efficacy of this technique
04 Potential for decreased cost of the procedure due to laser technique	15 Potential differences between clinical trials (efficacy) and community experience (effectiveness)
05 Potential for increased volume of this procedure due to new laser technique	16 FDA approval
06 Potential for decreased volume of this procedure due to new laser technique	17 Increased cost-effectiveness
07 Concern that coverage will prompt influx of new patients into insurance plan	18 Decreased cost-effectiveness
08 Benefits policy excludes procedure	19 Complications present a liability risk for the company
09 Denial of coverage may be legally challenged in the court system	20 Technique is outpatient rather than inpatient
10 Alternate technique available which is clinically proven effective	21 Technique is inpatient rather than outpatient
11 increased complication rate	22 Laser technique is potentially last resort
	23 What other carriers are covering
	24 Other

Most important consideration in favor of coverage	*(enter number)* _____	76.76
Second important consideration in favor of coverage	*(enter number)* _____	77.78
Third important consideration in favor of coverage	*(enter number)* _____	79.80
Fourth important consideration in favor of coverage	*(enter number)* _____	81,82
Fifth important consideration in favor of coverage	*(enter number)* _____	83,84
Most important consideration against coverage	*(enter number)* _____	86.86
Second important consideration against coverage	*(enter number)* _____	87,88
Third important consideration against coverage	*(enter number)* _____	99,90
Fourth important consideration against coverage	*(enter number)* _____	91,92
Fifth important consideration against coverage	*(enter number)* _____	93,94

6

Q-2 **Please record the two considerations that would be of least importance in favor of or against recommending coverage.**

Least important considerations in favor of coverage	***(enter number)_____***	95,96
	(enter number)_____	97,98
Least important considerations against coverage	***(enter number)_____***	99,100
	(enter number)_____	101,102

Q-3 **Does your company currently cover the use of a *lasar* for the following conditions? (Check yes or no)**

	(1) Yes (Covered)	(2) No (Not covered)	
Ablation of tatoos	____	____	103
Ablation of basal cell carcinoma of the skin	____	____	104
Diabetic retinopathy	____	____	105
Removal of colonic adenomas	____	____	106
Percutaneous coronary angioplasty	____	____	107
Percutaneous diskectomy	____	____	108
Photodynamic therapy for bladder carcinoma	____	____	109
Ablation of inoperable endobronchial carcinoma	____	____	110
Upper gastrointestinal hemorrhage	____	____	111
Ablation of carcinoma-in-situ of the cervix	____	____	112
Hemorrhoidectomy	____	____	113
Endometriosis	____	____	114
Stapedotomy	____	____	116
Removal of tonsils and adenoids	____	____	118
Ablation of urethral strictures	____	____	117

SECTION II: MEDICAL COVERAGE DECISION PROCESS

The following section contains a selection of questions covering the process for making medical coverage decisions within your company. There are also questions about the sources of information you utilize when making coverage decisions. Please read and answer these questions.

8

Q-1 What is your company's review process for making medical policy coverage decisions for a technology such as a laser?

__ (1) Reviewed by medical director alone 118
__ (2) Initially reviewed by medical director, but then always referred to another individual
__ (3) Initially reviewed by medical director, but then always referred to a Committee
__ (4) Initially reviewed by medical director, who then, at his/her discretion refers to another individual
__ (5) Initially reviewed by medical director, who then, at his/her discretion refers to a committee
__ (6) Other _____

If referred to a committee, approximately how many members does it have? (enter ~~number)~~ 110,120

Who are the members?

__ Chief executive officer or president 121
__ Benefits director or designee 122
__ Claims director or designee 123
Medical director 124
Medical director staff 125
__ Attorney 126
__ Medical Ethicist 127
__ Community physician 128
__ Utilization review representative(s) 129
__ Marketing representative(s) 130
__ Financial representative(s) 131
__ Other 132
_____

Q-2 Who is responsible in your company for making medical policy coverage decisions for a technology such as a laser?

(1) MediCal director alone 133
__ (2) A committee
__ (3) 0ther _____

Q-3 Who should optimally be responsible for making medical policy decisions relative to new technologies being used and reviewed for coverage?

(1) Medicai director alone 134
__ (2) committee
__ (3) Other _____
_____

Q-4 Are the majority of medical coverage policy decisions made in a: (choose one)

__ (1) Retrospective fashion 136
(after claims submitted or paid for)

__ (2) Prospective fashion
(before claims submitted or paid for)

Q-5 What do you consider the optimal timing for making medical policy decisions relative to new technologies being used and reviewed for coverage?

__ (1) Retrospective fashion 136
(after claims submitted or paid for)

__ (2) Prospective fashion
(before claims submitted or paid for)

9

Q-6 What sources of information do you use when reviewing a new technology such as a laser for the purpose of making a medical coverage policy decision? (Please rank top three from list provided below)

01 Government documents, i.e. , OHTA	07 Other larger insurers
02 FDA clearance document	08 Opinions of local expert physicians
03 Medicare policies	09 Medical society statements or practice guidelines, i.e. , AMA, ACS, ACP
04 Medical journals	10 NIH consensus conferences
os Insurer association information, i.e. , HIAA, TEC (BCBS)	11 Other _____
06 Opinions of national expert physicians	

Most used source *(enter number)* _____ 137,138
Second used source *(enter number)* _____ 139,140
Third used source *(enter number)* _____ 141,142

Q-7 What do you consider the optimal sources of information for making medical policy decisions for a new technology, such as a laser, being reviewed for coverage? (Please rank top three from list provided below]

01 Government documents, i.e., OHTA	07 Other larger insurers
02 FDA clearance document	08 Opinions of local expert physicians
03 Medicare policies	09 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP
04 Medical journals	10 NIH consensus conferences
05 Insurer association information, i.e., HIM, TEC (BCBS)	11 Other _____
06 Opinions of national expert physicians	

Most optimal source *(enter number)* _____ 143, 144
Second optimal source *(enter number)* _____ 146.146
Third optimal source *(enter number)* _____ 147,148

Q-8 When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following types of evidence? (Please rank the top three types from the list below)

1 Testimony or theory	6 Traditional review article
2 Randomized, controlled trial	7 Formal meta-analysis
3 Non-randomized, control lad trial	8 Retrospective, case-control study
4 Case series	9 Observational cohort study of patients receiving different therapies
5 Case reports/anecdotes	

First type *(enter number)*_____ 149
Second type *(enter number)*_____ 160
Third type *(enter number)*_____ 161

10

Q-9 For each type of evidence listed below, do you consider it: a) adequate in combination with other sources, and/or b) sufficient alone, to use when making a medical policy decision? (Please check either or both)

	Adequate, used in combination? (1)YES	(2)NO		Sufficient alone? (1)YES	(2)NO	
Testimony or theory		162		—	—	161
Randomized, controlled trial		163			—	182
Non-randomized, controlled trial		164			—	163
Case series		165			—	164
Case reports/anecdotes		166			—	165
Traditional review article		167			—	166
Formal meta-analysis		168			—	167
Retrospective, case-control study	—	169			—	168
Observational cohort study of patients receiving different therapies	—	160			—	169

Q-10 If cost-effectiveness data is available comparing the new laser therapy to the current standard of therapy, what do you consider necessary characteristics of the sources for the clinical safety and effectiveness data?

	Necessary? (1)YES	(2)NO	
Primary data in a clinical trial (vs secondary data analysis, e.g., decision analysis)	—	.	170
Multi-site study (vs single site study)	—	—	171
Published data (vs unpublished data)	—	—	172
Published in a US journal (vs published in a non-US journal)	—	—	173
Study conducted in the US (vs study conducted outside of the US)	—	—	

Q-1 1 If cost-effectiveness data is available comparing the new laser therapy to the current standard of therapy, what do you consider necessary characteristics of the sources for the cost data?

	Necessary? (1)YES	(2)NO	
Primary data in a clinical trial (vs secondary data analysis, e.g., decision analysis)	—	—	175
Multi-site study (vs single site study)	—	—	176
Published data (vs unpublished data)	—	—	177
Published in a US journal (vs published in a non-US journal)	—	—	178
Study conducted in the US (vs study conducted outside of the US)	—	—	179

Q-1 2 Assuming that a new therapy is equally safe compared to a standard therapy, IS your company likely to cover a new therapy which shows:

	(1)Yes	(2)No	
Equal effectiveness for equal cost?	___		180
Equal effectiveness for greater cost?			181
Equal effectiveness for lesser cost?	___	___	182
Less effectiveness for equal cost?	___	___	183
Less effectiveness for greater cost?		___	184
Less effectiveness for lesser cost?		___	185
Greater effectiveness for equal cost?	___	___	186
Greater effectiveness for greater cost?	___	___	187
Greater effectiveness for lesser cost?		___	188

Q-1 3 Which of the following considerations are the greatest barriers to establishing medical coverage policy in an optimal way? (Please rank the top three from list provided below)

1 Lack of timely effectiveness data	5 External regulatory barriers
2 Lack of timely cost-effectiveness data	6 Legal barriers
3 Lack of timely safety data	7 Provider contention/lack of support for coverage policy
4 Internal administrative barriers	8 Other _____

First barrier	*(enter number)* —	188
Second barrier	*(enter number)* —	190
Third barrier	*(enter number)* —	191

Q-1 4 **To what degree should the following parties have responsibility for assuring that technology used in medical practice yields reasonable benefits at reasonable costs?**

	No Responsibility	Little Responsibility	Some Responsibility	Moderate Responsibility	Great deal of Responsibility	
Federal Government	1	2	3	4	5	102
State Government	1	2	3	*4*	*5*	193
Health Care Institutions	1	2	3	4	5	194
Insurers	1	2	3	4	5	195
Practicing Physicians	1	2	3	4	5	196
Patients	1	2	3	4	5	197
Court System	1	2	3	*4*	*5*	198
Manufacturer	1	2	3	4	5	199

COMMERCIAL INSURERS

SECTION III: INSURER AND RESPONDENT CHARACTERISTICS

The following section contains a selection of questions covering characteristics of your company and yourself. Please read and answer these questions only in reference to your health insurance business. For these questions, "your company" refers to your central corporate office, if, for instance, you are located at a subsidiary office.

13

Q-1 What is the approximate number of current covered lives and/or claims processed last year by your company?

Covered Lives

__ (1) 0-250,000 200
__ (2) >250,000 - 500,000
__ (3) >500,000 - 1 million
__ (4) >1 million - 2 million
__ (5) >2 million - 5 million
__ (6) >5 million

Claims

__ (1) < 1 million 201
__ (2) > 1 million - 5 million
__ (3) > 5 million - 10 million
__ (4) > 10 million - 20 million
__ (5) > 2O million - 40 million
__ (6) > 40 million
__ (7) Data not available

Q-2 Approximately what percent of your covered lives are: (Estimate percentages, o-loo)

	Percent	
Children (< 18 years)	__ __ __	202-204
Young Adults (18-40 years)	__ __ .	205-207
Middle-aged Adults(41-64 years)	_____	208-210
Older Adults (>65 years)	__ __ __	211-213
	100	
Data not available	___	214

Q-3 What percent of the covered lives are in each type of health insurance listed below? (Estimate percentages,

Type of Insurance	Percent	
Individual Indemnity, other than HMO		215-217
Group Indemnity, other than HMO	__ __ .	218-220
HMO	__ . __	221-223
	100	

If you offer HMO coverage, what percent of the covered lives are the fallowing? (Estimate percentages, 0-100)

Type of HMO	Percent	
Staff model‡	__ __ __	224-226
Group model‡‡	__ . __	227-229
IPA model‡‡‡	__ __ __	230-232
Network model‡‡‡‡	__ __ __	233-236
	100	

Q-4 Does your company offer the following insurance products?

	(1) Yes	(2) No	
Preferred provider organization(PPO)*	__	__	236
Point-of-service plan(POS)**	__	__	237

‡ An organized prepaid health care system that delivers health services through a salaried physician group that is employed by the HMO.

‡‡ An organized prepaid health care system that contracts with one or more group practices, but primarily treats your HMO's enrollees.

‡‡‡ An organized prepaid health care system that contracts with one or more group practices, but the group provides care to patients who are not your HMO's enrollees.

‡‡‡‡ An organized prepaid health care system that contracts directly with physicians in independent practice, with one or more associations of physicians in independent practice , and/or with one or more multi-speciality group practices to provide health services.

* A product whereby a third-party payer contracts with a group of medical care providers who furnish services at lower than usual fees in *return* for prompt payment and a certain volume of patients.

** A product that offers the consumer a choice of options at the time he or she seeks services, rather than at the time of enrollment.

14

Q-5 **For what percent of the covered lives does your company assume full or partial risk versus assuming no risk, as in the case of self-funded employers, for which your company provides administrative services only? (Estimate percentages. 0-100)**

	Percent	
Full or partially insured	— — —	238-240
Administrative Services Only (ASO/CSO)	— — —	241-243

Q-6 **On what basis do the majority of your insurance policies have risk assessed? (Include ASO with non-HMO)**

Non-HMO		HMO	
(1) Full community rated	— 244	(1) Community rated	— 246
(2) Community rated by class	—	(2) Community rated by class	—
(3) Full experience rated	—	(3) Full experience rated	—

Q-7 **For which plans and/or products offered do you decide on medical policy coverage decisions?**

- — Staff model 2413
- — Group model 247
- — IPA model 248
- — Network Model 249
- — PPO product 250
- — Open-ended product 251
- — Traditional indemnity product 252

Q-8 **Are medical coverage decisions made similarly across the types of insurance for which you decide on medical policy?**

(1) Yes 26:
— (2) No

If no:

For which types of insurance do your responses in Section I and II apply?

- — Staff model 254
- — Group model 255
- — IPA model 256
- — Network Model 257
- — PPO product 258
- — Open-ended product 259
- — Traditional indemnity product 260

Q-9 **In which state(s) does your company have its largest enrollment? (Please rank the 3 states with the largest enrollment.)** 261-266

— (01) AK	— (08) DC	— (15) IL	— (22) ME	— (29) ND	— (36) OH	— (43) TN	— (50) WV
— (02) AL	— (09) DE	— (16) IN	— (23) MI	— (30) NE	— (37) OK	— (44) TX	— (51) WY
— (03) AR	— (10) FL	— (17) KS	— (24) MN	— (31) NH	— (38) OR	— (45) UT	
— (04) AZ	— (11) GA	— (18) KY	— (25) MO	— (32) NJ	— (39) PA	— (46) VA	
— (05) CA	— (12) HI	— (19) LA	— (26) MS	— (33) NM	— (40) RI	— (47) VT	
— (06) CO	— (13) IA	— (20) MA	— (27) MT	— (34) NV	— (41) SC	— (48) WA	
— (07) CT	— (14) ID	— (21) MD	— (28) NC	— (35) NY	— (42) SD	— (49) WI	

15

Q-10 How long has your company been in operation?

267

(1) < 1 year
(2) 1 -2 years
(3) 3 -5 years
(4) 6 - 9 years
(5) 10 - 20 years
(6) 20 - 50 years
(7) 50 - 100 years
(8) > 100 years

Q-1 1 is your company:

268

(1) for profit
(2) not for profit

Q-1 2 What are your professional/post-graduate degrees?

260-274

__ (1) M. D., D.O.
__ (2) Ph.D. or doctorate in biological science
__ (3) Ph.D. or doctorate In social science
__ (4) R.N.
__ (5) M.P.H.
__ (6) M.H.S.
__ (7) M.B.A.
__ (8) M. Sc.
__ (9) J. D.
__ (10) M.P.A.
__ (11) R.N.P.
__ (12) other _____

Q-13 If you are an M.D. or D. O., what is your medical specialty and, if applicable, sub-specialty?

276

_____

Q-14 How long have you served in your current or a similar position for an insurance company?

278

__ (1) < 1 year
__ (2) 1 -5 years
__ (3) 6 -10 years
__ (4) 1 1 -15 years
__ (5) 15 - 20 years
__ (6) > 20 years

Q-1 5 What is your job title?

277

_____

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE.

PLEASE ADD ANY ADDITIONAL COMMENTS ON THE BACK.

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Baltimore, MD 21205

12

HEALTH MAINTENANCE ORGANIZATIONS

SECTION III: INSURER AND RESPONDENT CHARACTERISTICS

The following section contains a selection of questions covering characteristics of your company and yourself. Please read and answer these questions only in reference to your health insurance business.

Q-1 What is the approximate number *of* current enrollees and/or claims processed by your company?

Enrollees		Claims	
(1) 0-19,999	200	(1) 0-19,999	201
(2) 20,000-49,999		(2) 20,000-49,999	
(3) 50,000-99,999		(3) 50,000-99,999	
(4) 100,000-249,999		(4) 100,000-249,999	
(5) 250,000-499,999		(5) 250,000-999,999	
(6) > 500,000		(6) >1,000,000	
		(7) Data not available	

Q-2 Approximately what percent of your enrollees are: (Estimate percentages, o-loo)

	Percent	
Children (<18 years)	___	202-204
Young Adults (18-40 years)	___	205-207
Middle-aged Adults(41-64 years)	___	208.210
Older Adults (>65 years)	___	211-213
	100	
(1) Data Not Available	___	214

Q-3 Which HMO plan(s) does your company represent? (Estimate percentages in terms of enrollees, 0-100)

Type of HMO	Percent	
Staff model*	___	21s-217
Group model**	___	218-220
IPA model***	___	221.223
Network model****	___	224.228

Q-4 Do you offer any of the following non-traditional products? (Estimate percentages in terms of enrollees 0-100)

	Percent	
Open Ended Product#	___	227-220
Preferred Provider Product##	___	230-232
Traditional Indemnity Product###	___	233.236

*An organized prepaid health care system that delivers health services through a salaried physician group that is employed by the HMO.

** An organized prepaid health care system that contracts with one independent group practice to provide health services.

*** An organized prepaid health care system that contracts with two or more independent group practices to provide health services.

**** An organized prepaid health care system that contracts directly with physicians in independent practice, with one or more associations of physicians in independent practice , and/or with one or more multi-speciality group practices to provide health services.

A product where individuals are enrolled in the HMO, but may self-refer to providers outside the network, typically with deductibles or extensive cost sharing required.

A product whereby a third-party payer contracts with a group of medical care providers to furnish services at lower than usual fees in return for prompt payment and a *certain* volume of pet i rots.

A product where benefits are paid in a predetermined amount in the event of a covered loss.

14

Q-5 **Which payment method is used for the *primary care and specialty care physicians* in your HMO? (Estimate percentages. 0-100)**

Primary Care Physicians	Percent		Specialty Care Physicians	Percent	
Salary	— — .	230-230	Salary	— — .	246-241
Capitated payment	— — —	230-241	Capitated payment	— — —	248-250
Payment-for-service	— — —	242-244	Payment-for-service		261-263

Q-6 **For which plans and/or products offered do you decide on medical policy coverage decisions?**

— Staff model 254
— Group model 255
— IPA model 256
— Network Model 257
— PPO product 258
— Open-ended product 259
— Traditional indemnity product 260

Q-7 **Are medical coverage decisions made similarly across the types of insurance for which you decide on medical policy?**

(1) Yes 261
(2) No

If no:

For which types of insurance do your responses in Section I and II apply?

— Staff model 262
— Group model 263
— IPA model 264
— Network Model 265
— PPO product 266
— Open-ended product 267
— Traditional indemnity product 268

Q-8 **In which state(s) does your company have its largest enrollment? (please rank the 3 states with the largest enrollment.)** 269-274

(01) AK — (02) AL — (03) AR — (04) AZ — (05) CA — (06) CO — (07) CT
(08) DC — (09) DE — (10) FL — (11) GA — (12) HI — (13) IA — (14) ID
(15) IL — (16) IN — (17) KS — (18) KY — (19) LA — (20) MA — (21) MD
(22) ME — (23) MI — (24) MN — (25) MO — (26) MS — (27) MT — (28) NC
(29) ND — (30) NE — (31) NH — (32) NJ — (33) NM — (34) NV — (35) NY
(36) OH — (37) OK — (38) OR — (39) PA — (40) RI — (41) SC — (42) SD
(43) TN — (44) TX — (45) UT — (46) VA — (47) VT — (48) WA — (49) WI
(50) WV — (51) WY

Q-9 **How long has your company been in operation?**

276

(1) 1 year
(2) 2 - 3 years
(3) 4 - 7 years
(4) 8 -15 years
(5) 16 -20 years
(6) 21 -50 years
(7) > 50 years

15

Q-10 Is your company:

(1) for profit
(2) not for profit

276

Q-11 What are your professional/post-graduate degrees?

277-282

__ (1) M.D., D.O.
__ (2) Ph.D. or doctorate in biological science
__ (3) Ph.D. or doctorate in social science
__ (4) R.N.
__ (5) M.P.H.
__ (6) M.H.S.
__ (7) M.B.A.
__ (8) M. Sc.
__ (9) J.D.
__ (10) M.P.A.
__ (11) R.N.P.
__ (12) other _____

Q-12 If you are an M.D. or D. O., what is your medical specialty and, if applicable, sub-specialty?

_____ 263

_____ 284

Q-13 How long have you served in your current or a similar position for a carrier?

286

__ (1) < 1 year
__ (2) 1 -5 years
__ (3) 6 -10 years
__ (4) 11 -15 years
__ (5) 15 - 20 years
__ (6) > 20 years

Q-14 What is your job title?

_____ 286

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