In this chapter, we describe and interpret our interviews with representatives of nine managed care organizations. We begin by providing background on how the managed care organizations were selected and recruited to participate, and the issues addressed in the interviews. We then report and interpret their experiences with emerging medical technologies. As with manufacturers, the discussion is somewhat general in order to avoid inadvertently revealing the identity of any participating managed care organization. Despite this limitation, we believe we convey various ways that MCOs handle emerging technologies.

BACKGROUND ON MCO INTERVIEWS

Recruitment of Interview Respondents

To understand how MCOs respond to the availability of new medical technologies, we sought to interview managed care organizations representing a substantial proportion of the managed care market in California.\(^1\) We sought to interview a selection of organizations with

\(^1\)The study focused on managed care organizations in California because of the interests of the sponsoring California Goldstrike Partnership. California is a national leader in the development and growth of managed care and has a high managed-care-penetration rate. Specifically, of Californians who receive their health insurance coverage through employers, 63 percent are enrolled in HMOs, another 23 percent receive their health care through Preferred Provider Organizations (PPOs), and only 7 percent have health care coverage through traditional indemnity insurance plans (Enthoven and Singer, 1998). The experience to date of California plans is not necessarily representative of managed care plans nationally, especially because of the high prevalence
financial responsibility and decisionmaking authority for coverage decisions, including large and medium or small MCOs and capitated medical groups contracting with MCOs.\textsuperscript{2} To learn more about factors operating at a national level and to explore the interplay between national and local MCO decisionmaking and coverage policy, we included some plans associated with national organizations.

We identified potential MCO respondents using the 1998 California Managed Care Survey.\textsuperscript{3} Once identified, RAND investigators contacted MCO staff to request an interview. Chief executive officers or medical directors of each MCO and capitated medical group received a letter or fax from RAND including a description of the project and its goals (Appendix A) and a description of the interview, together with a list of interview questions (Appendix C). We encouraged MCOs to use specific devices as examples in describing their processes. In particular, we asked them to think of emerging technologies for which the coverage or medical-necessity decisionmaking process had been unusually difficult.

Content of the Interviews

As detailed in Appendix C, the interviews with MCOs addressed five sets of issues:

- The extent of formal technology assessments of new medical devices, the processes employed for those assessments, and the role of manufacturers
- How the MCO makes coverage decisions for procedures involving emerging medical devices

\textsuperscript{2}We focused on organizations that are responsible for both providing care and assuming financial risk. For a study that compares the experiences of such organizations with indemnity insurers, see Powe et al. (1996). For a study comparing reliance on technology assessment of decisionmakers in hospitals, HMOs, and third-party payers, see Luce and Brown (1995).

\textsuperscript{3}This survey contains profiles of every significant managed care organization—including HMOs, PPOs, Medicare and Medi-Cal risk plans—operating in California, including information on statewide enrollment. The survey is published in a supplement to California Medicine.
- How the MCO sets payment or reimbursement levels for medical devices
- How case-by-case medical-necessity determinations are made
- Lessons learned and advice for medical device manufacturers.

Of the eleven MCOs and three capitated medical groups we approached, we were able to interview eight MCOs and one capitated medical group. Typically, one respondent represented each MCO: the medical director or chief medical officer. We conducted all of the interviews by telephone, and they lasted about 45 minutes each. As with the manufacturer interviews, respondents were promised confidentiality and were told they were free to decline to discuss sensitive or proprietary information. We used the questions in Appendix C as the guide and generally proceeded in the order in the protocol. As with the manufacturers, in no case did any respondent refuse to address any topic included in our protocol, nor did they seem reluctant to reveal information about their internal processes of TA and coverage decisionmaking.

**Descriptions of the MCOs Interviewed**

All of the MCOs we studied were based in California, although several respondents described procedures of national organizations with which they are affiliated. Respondents represented five of the ten largest MCOs in California, all with statewide enrollments of

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4In our initial round of telephone calls, several MCO representatives declined to participate, and two of the three capitated medical groups we approached declined to participate, reporting that they did not do their own technology assessments. Two other studies reported in the literature employed semi-structured interviews of key decisionmakers. Weingart (1993) studied technology decisionmaking in medical centers, and Luce and Brown (1995) studied technology assessment by hospitals, HMOs, and third-party payers. Neither reported the extent of refusals to participate among potential respondents contacted. Response rates for other mail surveys, such as the survey reported in Powe et al. (1996) and in Steiner et al. (1996, 1997), are generally disappointing (e.g., 41 percent). Yet, these studies and our study include major MCOs covering the majority of health plan enrollees nationally, and in California, respectively.

5Other studies of technology assessment have also relied on medical directors as the key respondents. Steiner et al. (1996) report that 70 percent of respondents to their national mail survey of private health insurers were medical directors.
more than 1 million. We also interviewed medical directors of three MCOs with statewide enrollments between 75,000 and 150,000, and the medical director of one large capitated medical group. These MCOs represent a mix of for-profit and non-profit organizations, had private-sector and public-sector (e.g., Medicare, Medicaid) enrollees, and offered various insurance products (Health Maintenance Organization [HMO], Preferred Provider Organization [PPO], Medicare HMO, Medi-Cal HMO) in California.

**RECENT MCO EXPERIENCES WITH TECHNOLOGY ADOPTION**

MCOs described a multilayered process of decisionmaking that results in a procedure, and any devices involved, becoming eligible for payment or reimbursement. According to the MCO respondents, decisions about technology adoption involve interpretation of contract language ("business" decisions), as well as assessment of whether the medical procedure represents the standard of care ("medical" decisions). A threshold question for the MCO is, "Does the payer’s contract specifically exclude the procedure or device?" If the medical procedure or the device is specifically excluded, there may be no need for further review. If the procedure is not specifically excluded by the payer’s contract, the MCO then needs to make a decision about whether to pay for use of the procedure. This process is generally referred to by MCOs as coverage decisionmaking.

To make a coverage decision, MCOs often employ technology assessment to evaluate the properties of a medical technology, assessing the safety, effectiveness, and indications for that technology’s use. Technology assessments may be formal, involving various staff

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6MCOs reported that they evaluate medical procedures and not devices per se. In reviewing a medical procedure, they consider evidence about any device or devices used in the treatment.

7The contract between the payer (typically an employer) and the managed care organization articulates the rights and responsibilities and the flow of funds and assignment of financial risk. Most important in this context, it defines the covered health benefits.

8Payers’ contracts determine what services will be covered, unless the contract appears to be in conflict with a government mandate or there are concerns about possible litigation if coverage is denied. See, for example, Havighurst (1995).
and one or more committees, or they may be informal, performed, for example, entirely by the MCO medical director. Coverage decisions are based on the evidence incorporated in the technology assessment and on contract interpretation. These decisions determine whether a procedure is experimental or investigational or represents the standard of care. A positive decision on coverage does not mean that every enrollee has access to the procedure, however. If a positive coverage decision is made, MCOs have processes for determining whether the procedure is medically necessary in particular cases.

**Triggers for Formal Coverage Decisionmaking**

Our MCO respondents reported that they generally lack systematic surveillance mechanisms for new technologies, which makes them reactive rather than proactive. They tend to react to triggers such as physician and patient demand, prior-authorization requests, and claims submitted without a CPT code. MCOs report being influenced by their competitors only indirectly. Specifically, when several of their physicians report receiving payment from one of their competitors, an MCO is likely to assess whether it should cover the procedure. Whether a procedure is considered for a formal technology assessment depends on the number and pattern of requests. A large number of requests, several requests from a particular provider (indicating that a new device is being tried), or even a single request may trigger a technology assessment. Owing to time and staffing

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9As described in Chapter Three, new technologies often are introduced into managed care systems largely without the knowledge of MCOs and without any conscious decisions about adoption. This "under-the-radar" phenomenon has been described in other studies; for example, Powe et al. (1996) report that health care plans were often not aware that a physician was using a new technology if it was billed using a standard billing code. In this chapter, we report on MCO experiences in making explicit decisions about technology adoption.

10From a national survey of health plans, Powe et al. (1996) report that provider queries (85 percent), higher-than-usual charges (57 percent), utilization review activities (48 percent), and patient queries (33 percent) were the most frequently cited factors alerting health plans to the use of new laser technologies.

11Single requests tend to trigger technology assessments only when the MCO believes that the procedure may be experimental or investigational. Similarly, Powe et al. (1996) report that the single-most-important clinical factor prompting medical directors of health plans to make a specific coverage decision on laser angioplasty technology was the belief on the part of the medical director that the procedure might be
constraints, not all procedures are given a formal review; however, all MCOs have processes for making coverage decisions in the absence of a formal technology assessment.

**The Technology Assessment Processes of MCOs**

The formal technology assessment process varies widely across MCOs, according to our respondents. Aspects that vary include the following:

- The level of formality, including whether the MCO uses staff in addition to the medical director and one or more standing committees to conduct the technology assessment.
- The level of responsibility for decisionmaking—for example, whether the decisions are made by the national headquarters or by the local health plans.
- The rigor—depth and breadth—of the review of medical evidence.

Other important clinical factors include complication rates and questions about whether the technology reflected standard practice in the community.

For detailed descriptions of formal technology-assessment processes, see Braslow et al. (1998) describing United HealthCare's TA process and Parrish (1998) describing the TA process used by Blue Shield of California. NIHCM Foundation (1999, pp. 11–13) provides less-detailed descriptions of the coverage decision processes of Highmark Blue Cross Blue Shield, and Blue Cross of California.

The medical director is a key participant in the process of technology assessment in all of the MCOs interviewed for our study. However, there was great variability in the number and types of additional staff and committees involved in the process. Some MCOs have multiple layers of review. Steiner et al. (1996) reported that 92 percent of respondents in their national mail survey indicated that the medical director was directly involved in the review process. Forty-six percent indicated that it was left to the medical director's discretion to decide when to refer the decision to a committee or another staff member in the health plan.

MCOs rely on a variety of sources of information, including, but not limited to, journal articles retrieved through Medline searches, government-agency (FDA, HCFA, and AHRQ) materials, information supplied by manufacturers, TAs performed by other insurers, and opinions of national and local experts. Similarly, Steiner et al. (1996) report that the most frequently ranked sources of information used by health plans are medical journals, opinions of local experts, FDA clearance documents, and information from plan associations such as Blue Cross and Blue Shield.
• The use of outside expertise and resources, including technology-assessment organizations such as ECRI and Hayes, Inc., and national or local physician experts
• The extent to which MCOs are influenced by government agencies, such as AHRQ (formerly AHCPR) and HCFA, and health insurance industry leaders
• The average number of formal technology reviews conducted each year.  

Some aspects of the technology assessment processes are common across MCOs. Typically, for example, FDA approval of the medical device involved in the procedure is necessary before a technology assessment will be performed. FDA approval is considered by all MCOs to be necessary but not sufficient for their purposes. All MCO respondents also reported that their staff conduct literature searches using the National Library of Medicine’s Medline search engine, and gather other information, including information from the manufacturers. The medical director and other MCO staff then weigh the strength of the evidence, although some MCOs employ more-systematic procedures than others do. MCO respondents report using outside sources most often when a Medline search produces conflicting information or when the decision is especially difficult.

Participation of Manufacturers in the TA Process

Most formal TA processes are “closed”: Manufacturers may submit written materials but are not allowed to participate directly in the

15 There was a wide range in reported numbers of formal technology assessments per year. Most MCOs reported between three and 15, with one MCO reporting 36.
16 Several MCO respondents noted that the FDA reviews devices with a focus on safety, and to some extent efficacy (effects under clinical trial conditions), but not effectiveness (under routine clinical practice conditions) or cost-effectiveness. Thus, they believe FDA approval is only a starting point. They report, with a sense of frustration, that many manufacturers seem perplexed by their unwillingness to accept FDA approval as sufficient for coverage.
17 For example, when procedures are in the process of evolving from being considered experimental to representing the standard of care or standard practice in that community.
decisionmaking process. Of the nine MCOs we interviewed, only two reported that manufacturers were invited, at least on occasion, to participate in the TA committee process.

MCO respondents also characterized the information provided by manufacturers. On the one hand, most MCO respondents viewed information provided by manufacturers as a “useful starting point.” Several expressed the general attitude that, “if they have information, we’d love to see it.” On the other hand, many of the MCO respondents regarded literature reviews produced by manufacturers somewhat skeptically. Respondents noted that manufacturers usually did not report the keywords used in computer-aided literature searches, making it difficult for MCOs to assess the quality of the literature review. MCO respondents generally expressed concern that manufacturers tend to include studies that support their position and ignore evidence that might undermine their arguments. Medical directors stated that they accord the same weight to manufacturer-supported, peer-reviewed studies as to other such studies, but review the design and methodology especially carefully.18

Most MCO respondents expressed a desire for less marketing on the part of the manufacturers. Most medical directors did not believe that the technology-assessment process was an appropriate forum for a sales pitch. One medical director summed it up this way: “The harder they push, the more resistance they’ll get.”19

Nonmedical Factors Affecting Coverage Decisions

MCOs also consider nonmedical factors in making coverage decisions. Nonmedical factors considered by our MCO respondents include the following:

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18Similarly, participants in a recent symposium expressed the view that, if scientific evidence comes solely from “advocates” (such as manufacturers), “it is critical to evaluate the validity of the evidence, including whether the studies conform to FDA regulations” (NIHCM Foundation, 1999, p.32).

19One MCO respondent said that he and his colleagues prefer “permission marketing,” which he described as “letting the device speak for itself.” He suggested that manufacturers allow MCOs to get some experience with the device and wait for MCOs to approach them for information—in effect, inviting the manufacturer to market the product then.
state insurance mandates and other state regulatory requirements
• publicity about and controversy surrounding a procedure or medical device
• demand for a technology among patients and physicians
• competition with other health plans\(^{20}\)
• potential for litigation.\(^{21}\)

Generally, MCO medical directors suggest that medical factors—evidence from the technology assessment—carry the greatest weight in decisionmaking, but that nonmedical factors can also be important, especially publicity or controversy that may result in a high level of demand from patients and physicians, including some demand viewed as inappropriate by some medical directors.\(^{22}\)

### Reconsideration of Coverage Decisions

Negative coverage decisions are sometimes reconsidered if important new data emerge, if there is continued physician or patient demand, or if the MCO decides that covering an emerging technology would confer a market advantage. In addition, some regulatory and accreditation bodies require periodic reconsideration. Medical directors do not routinely report negative coverage decisions to manufacturers, and no medical director suggested that manufacturers have any effect on whether they reconsider a coverage decision.

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\(^{20}\)One MCO respondent, reflecting on the issue of competition, said, “We don’t want to get out too far ahead but we don’t want to lag too far behind either.”

\(^{21}\)MCOs want to use processes that will result in fair decisions that can be supported in the face of litigation. Documentation of decisionmaking is critical in the litigation context.

\(^{22}\)Powe et al. (1996) also report on the importance of nonmedical factors in coverage decisionmaking. The nonclinical factors most often cited by their health plan survey respondents included high potential cost (36 percent), possible liability risk (15 percent), and the percentage of the insured population that would be affected (13 percent).
Determining Payment Levels for New Devices

After making a coverage decision (whether that decision is based on a formal technology assessment or on a more informal process), the MCO must set a payment level. Medical directors reported that they are not directly involved in determining payment rates, but stated that payment levels generally reflect market forces. Pricing is often based on the existence and price of alternatives and on the projected use of the product. With new devices, the MCO may price based on a similar product. For very novel devices, which are more difficult to price, the MCO may use Medicare reimbursement rates or attempt to negotiate with the manufacturer on the basis of volume.\(^{23}\)

Case-by-Case Determinations of Medical Necessity

MCO respondents reported that they typically develop patient-selection criteria and disseminate medical indications for procedures that have received coverage approval. These materials usually are disseminated either electronically or on paper to their physicians and physician groups. Most MCOs make case-by-case medical-necessity determinations locally, even if coverage decisions are made nationally.\(^ {24}\) MCOs that provide care through contracts with capitated medical groups may delegate medical-necessity decisions to them.\(^ {25}\)

\(^{23}\)Powe et al. (1996) concluded that some health plans may attempt to use payment policy rather than coverage policy to control the use of emerging medical technology. They warn that such an approach could result in lower-cost, but less-effective, technologies proliferating at the expense of more-costly, but more-effective, alternatives.

\(^{24}\)There is substantial confusion and disagreement about the meaning of the term “medical necessity.” (For example, NIHCM Foundation, 1999, pp. 25-29.) We did not provide a definition of “medical necessity” to respondents, and none asked for a definition. Apparently, the term is not ambiguous to any of the medical directors we interviewed, although we did not explore how much disagreement there might be among them.

\(^{25}\)Because capitated medical groups bear the financial risk by accepting a flat fee to provide covered benefits to a specific group of individuals, MCOs are not at risk for the costs of specific procedures and may therefore delegate the decisionmaking to the medical group, which has assumed the risk. Some of our respondents noted that tensions can arise between the health plan and the medical group when, for example, a patient successfully appeals a coverage denial by the medical group to the health plan, and the medical group bears the financial cost. This concern was also raised in the symposium summarized in NIHCM (1999, p. 14).
Medical directors report that these decisions can be especially difficult when the patient or the physician argues on what MCOs view as “nonmedical” grounds. Some MCO respondents referred to arguments made on nonmedical grounds as “quality-of-life” arguments and others referred to them as “convenience” arguments. Some participants at the October 7 meeting expressed confusion about the distinction between quality of life and convenience and suggested that some MCO decisionmakers characterize some advantages for patients as “nonmedical” when, in fact, they involve genuine medical concerns.

Denials of coverage can also be difficult in cases of life-threatening illnesses. In all cases, patients have the right of appeal for denial of coverage. In California, if the procedure has to do with a life-threatening condition, patients have special rights. At least one MCO reported that if the procedure is requested for a patient with a terminal condition, the MCO automatically sends the patient’s appeal for external review. Terminal conditions pose especially difficult situations for MCOs, because decisions must often be made very quickly.

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26 One MCO medical director used the example of an insulin pump, arguing that a diabetic patient may want the pump for its greater convenience, even though his or her condition was controlled with injectable insulin. The MCO would be under pressure in that situation to approve the use, even though the device was not believed to be medically necessary.

27 Braslow et al. (1998) discuss the need to assess the “medical appropriateness” of the procedure as a part of the TA process. They define medical appropriateness as ensuring that “the expected health benefits from a medical service are clinically significant and exceed health risks by a sufficiently wide margin so that the service is demonstrably worthwhile and superior to other services (including no service).” They define clinical significance as including such outcomes as increased life expectancy, improved functional capacity, prevention of complications, or relief of pain. If one accepts this definition of clinical significance, one might argue that these outcomes are clearly medical outcomes; yet, it could be argued that the relief of pain could also be considered a quality-of-life outcome. We are unaware of any clear, widely accepted distinctions between medical and nonmedical outcomes or between convenience and quality of life.