



Changes in  
**HEALTH CARE**  
**FINANCING &**  
**ORGANIZATION**

# findings brief

## How Do MCOs Decide Whether an Intervention is Medically Necessary?

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Medical directors consult a number of sources to define coverage limits for new and standard medical interventions, including technology assessment reports, the results of randomized trials, and professional guidelines, according to the findings of a research project funded by The Robert Wood Johnson Foundation's Changes in Health Care Financing and Organization (HCFO) initiative. The vast majority of medical directors reported that cost considerations also entered into their decision-making process.

In addition, the research indicated that state regulators and health plan directors have very different ideas about what the terms "medical necessity" and "coverage" mean and how they should be applied. Even among themselves, regulators and plan directors don't always reach consensus on these definitions. Regulators tend to disagree more broadly about them than do medical plan directors.

Stanford University's Linda Berghold, Ph.D., Alan Garber, M.D., Ph.D., and Sara Singer, MBA, conducted the investigation to seek systematic and valid information about medical necessity and coverage decision-making in the national managed care market and the state organizations that regulate managed care products. They were prompted in part by the findings of a 1999 study,

which was coauthored by Singer and Berghold, indicating that the use of the term "medical necessity" to define coverage limits was arbitrary and highly variable among managed care organizations (MCOs) in California, resulting in potentially different decisions about a single case.<sup>1</sup> "We were interested in knowing just how unique the California findings were and whether other regions of the country would report the same type of variation," says Berghold.

### Background

In the years preceding the managed care era, insurance companies made more open-ended decisions about which health services to cover, and received relatively little scrutiny about the choices they made. When managed care became the dominant form of health care, health plans were forced to open their decision-making process to an unprecedented level of examination by the public and policymakers. At the same time, consumers began to challenge the industry, particularly in the area of coverage denials and appeals. The public was no longer content to leave their health plans to determine which interventions were necessary. State legislatures and Congress responded to these pressures with several proposals to reform managed care, most of which were implemented before legislation could be passed. One area that remains unclear, how-



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AcademyHealth is the national program office for HCFO, an initiative of The Robert Wood Johnson Foundation.

ever, is the decision-making process surrounding denials of coverage that are appealed. Who should decide which services are medically necessary and under which circumstances? What evidence should be used to guide the decision? Should cost be considered? These are a few of the questions that Berghold and her colleagues set out to answer.

### Methods and Results

The researchers designed two national surveys to elicit key information from medical directors and state regulators concerning:

- the type of evidence and cost-effectiveness information used to evaluate standard and new interventions for coverage;
- the actual, as well as preferred, criteria included in medical necessity contractual standards;
- regulatory oversight in these areas; and
- the support for national standards and uniformity in the definition and application of medical necessity.

#### Medical Director Survey

Enlisting the help of Freeman, Sullivan & Co., a professional survey firm, the researchers received responses from 65.9 percent of medical directors from 346 health plans in 49 states and the District of Columbia who met the study's inclusion criteria. The survey included questions about the health plan and its operations, as well as utilization and quality management tools, the use of evidence and cost information in evaluating medical interventions and in formulating contractual definitions, and the impact of external forces on the decision-making process. The medical directors were also asked about their own contractual definitions of medical necessity. Finally, they were asked to recommend approval or denial of a specific case based on their own medical necessity criteria.

More than half of the medical directors said that, when evaluating new interventions, they favor the use of technology assessment reports from public and private organizations such as BCBS TEC,<sup>2</sup> ECRI,<sup>3</sup> Hayes,<sup>4</sup> and Medicare. They also consult randomized controlled clinical trials when available, and, to a lesser extent, professional guide-

lines and expert opinions. Community standards of care were rarely cited as a preferred source of evidence. Ninety percent of medical directors reported that cost was a factor in the decision-making process; more than half reported that their plans would consider a less costly, equally effective intervention before a more costly one in making a coverage decision about a new intervention.

#### Regulator Survey

A second survey targeted 65 state regulatory agencies in 49 states and the District of Columbia.<sup>5</sup> At least one regulator in every state responded to questions closely matched to those in the medical director survey, such as queries about the way the regulatory agency defined terms such as “coverage” and “medical necessity,” and whether and how they monitored or regulated the use of evidence, cost criteria, contractual definitions, practice guidelines, preauthorization, timing of denials, external review, and a number of other issues.<sup>6</sup> “We wanted to understand the way regulators addressed these issues, how it varies by state, and whether the regulation has an impact on plans, contracts, or decision-making practices,” says Singer.

Most significant among the results was the lack of consistency between how medical directors and regulators define and apply the terms “medical necessity” and “coverage.” Also striking was the diversity among state regulators themselves in the way they understand these terms. Such variation makes it difficult for consumers, health plans, and regulators to operate under a cohesive “coverage-decision” framework, and subjects national managed care plans to a patchwork of regulations that differ from state to state.

The researchers also found that regulators focus less on the clinical factors that may underlie coverage choices in each specific case than on applying a broad set of predetermined rules for how decisions should be made. Because the regulatory process differs among states, however, this approach likely results in variability of consumer protection. Thus, plans may not be implementing policies based on the best available clinical and cost-effectiveness evidence.

Several key policy questions emerged from this research, including:

- In light of the variation among plans in the way evidence is used and applied in coverage decision-making, how can more consistency be encouraged?
- Should every state or managed care plan be required to adopt a uniform definition of medical necessity?
- Are some considerations about cost more appropriate than others when making coverage decisions?

A number of policy questions were raised through the survey of state regulators, such as:

- What is the appropriate role for state regulation vis-a-vis managed care practices?
- Should states advocate for more rigorous and evidence-based decision-making in managed care?
- How can more consistency in the regulation of managed care be encouraged?

### Research Dissemination Conference

As the researchers neared the end of their project, they tested their findings among a group of key stakeholders at a dissemination conference in Annapolis, Md., that was funded by the Agency for Healthcare Research and Quality. Conference participants were asked to consider the research findings, discuss their day-to-day implications, and outline potential policy initiatives.

The participants agreed on the need for clarity and consistency in defining medical necessity and making coverage decisions, but there was no consensus about how to reach that goal. Some participants wanted

more government intervention to achieve consistency, while others preferred market efforts. The discussion underscored the challenges that medical directors and regulators face as they try to operate in an environment that does not encourage collaboration or offer many opportunities for stakeholders to meet and understand each other's point of view.

### Conclusion

As managed care reform legislation is developed, these findings may assist policymakers in creating more consistency relative to how decisions about medical intervention and coverage are made. In addition, the findings may prompt more collaboration between regulators and plan medical directors to resolve coverage issues at the state level and improve policies and compliance. "We hope that the stakeholders will support increased consistency in the definition and application of 'medical necessity' and that some resolution may result over issues such as the use of scientific evidence and consideration of cost/benefit tradeoffs in coverage and medical necessity decision-making," says Garber.

NOTE: A full description of the researchers' surveys, findings, and recommendations can be found in two articles at [www.hcfo.net/pdf/singer/pdf](http://www.hcfo.net/pdf/singer/pdf), and [www.hcfo.net/pdf/bergthold/pdf](http://www.hcfo.net/pdf/bergthold/pdf).

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### About the Author

Bonnie Austin is a senior associate working primarily on The Robert Wood Johnson Foundation's HCFO program, which supports

investigator-initiated research and policy analysis, evaluation, and demonstration projects examining major changes in health care financing and their effects on cost, access, and quality. AcademyHealth ([www.academyhealth.org](http://www.academyhealth.org)) serves as the national program office for HCFO. Ms. Austin can be reached at 202.292.6700; [bonnie.austin@academyhealth.org](mailto:bonnie.austin@academyhealth.org).

### Endnotes

- 1 Results of the California study are available on the Center for Health Policy Web site, <http://chppcor.stanford.edu> under "Research" and primary author Sara Singer. Additional analysis is available in Singer, S. and L. Bergthold, "Prospects for Improved Decision Making About Medical Necessity," *Health Affairs*, Vol. 20:1, January/February 2001.
- 2 BlueCross BlueShield Technology Evaluation Center.
- 3 ECRI is a nonprofit international health services research agency and a collaborating center for health technology assessment of the World Health Organization.
- 4 Hayes, Inc. tracks new and emerging health care technologies that are judged to have a potentially significant impact on health care costs, utilization, and/or quality. Hayes provides a wide spectrum of health technology information services, including customized technology assessment reports, and training in medical literature searching, study design and methodology, data analysis, epidemiological principles, and applied technology assessment.
- 5 Alaska is not included; that state does not have an agency that performs the type of regulation that was the focus of the survey.
- 6 A compendium of the regulatory survey responses is available at [www.hcfo.net/pdf/stanford.pdf](http://www.hcfo.net/pdf/stanford.pdf).



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