MEDICAL NECESSITY: DO WE NEED IT?

by Linda A. Bergthold

Prologue: For more than thirty years public and private health insurance plans have used the term medical necessity as a place holder to define the limits of their benefit coverage, despite widespread disagreement about its meaning. Initially, medical necessity was used to ensure that providers were paid for services performed. Now, Linda Bergthold argues, it is used primarily as a tool to control the use of scarce resources. Medical necessity has assumed greater importance, particularly because of the growth in managed care and integrated health systems and the development of expensive new technology and treatments. Because this term is undefined and thus open to interpretation, its use as the basis of coverage decisions can result in costly litigation to resolve disputes among providers, payers, and patients. Several questions must be addressed: What criteria must a treatment, service, or supply meet to be covered by insurance? Who should make these decisions? Finally, how should conflicts be resolved? In this paper, which was presented at an April 1995 symposium on medical necessity sponsored by the National Institute for Health Care Management and the Agency for Health Care Policy and Research in Washington, D.C., Bergthold discusses the historical and current use of medical necessity and the impact of the national health care reform debate on the term. She also suggests ways to clarify the term and presents alternatives to replace it altogether. Bergthold is a vice-president of Lewin-VHI, in Sausalito, California. She works in the firm's public policy and health care organization practices, focusing on state health care reform, benefit design, and strategic planning. Prior to this, she was a principal of William M. Mercer, Inc., in San Francisco. She served on the White House Health Care Reform Task Force as cochair of the working group on benefits coverage. Bergthold holds a doctorate in sociology from the University of California, Santa Cruz.
Abstract: The term medical necessity has been mainly a placeholder in insurance plans for over thirty years. More recently, the national health care reform debate and litigation over denials of costly experimental treatments have broken the term out into open discussion about what a necessary service is and who should decide if it is covered. This paper summarizes the history of the term and its evolution from an insurance concept controlled by practicing physicians to a rationing tool used by insurance administrators. How did national reform efforts address this terminology, and how should we define medical necessity in a changing delivery system?

The term medical necessity is rarely defined, largely unexamined, generally misunderstood, and idiosyncratically applied in medical and insurance practice. For years it has been mainly a placeholder in insurance plans. It has covered a wide area of ambiguity, allowing insurance companies to define their benefit coverage by relying on the professional judgment of physicians to determine the nature of a medically necessary service, supply, or procedure. Occasionally, it has become the object of legal dispute when physicians, insurance companies, or patients have disagreed on the coverage of a specified treatment. More commonly, it has rested within coverage policies, wrapped in a cocoon, waiting for the pressure of a lawsuit to break it out into open discussion.

In the past few years, however, medical necessity has become a central focus of dispute. Denials of coverage for costly experimental treatments have been litigated and widely publicized; state and national health care reform efforts have prompted public discussions about which services should be covered in a basic benefit package and which standards should be used to define a covered service; the growth of integrated health plans and capitated payment systems has blurred the lines between traditional insurers and providers and thus obscured accountability for coverage decisions; and the development of new technology and new treatments has forced patients, their physicians, and insurance companies to confront tough decisions about appropriateness, efficacy, and relative costs. Medical necessity has become a major tool for allocating health care resources in a time of increasing costs. It deserves closer scrutiny.

This paper summarizes the history of the term as it has been used in public and private health plans and the way in which it has evolved from an insurance concept controlled by practicing physicians to a rationing tool largely under the control of insurance plan administrators and their medical directors. I describe how the national health care reform debate addressed the definition of medical necessity and to whom the definitions are important, and I propose some clarification of the meaning of medical necessity within a changing delivery system.

Origin and definitions. There is probably no one person who can recall the day that medical necessity was born. It emerged during the development of private insurance in the 1940s, to ensure that hospitals and physicians
were paid for the services they performed. During that time insurers accepted the decisions of physicians about what was medically necessary without much question. The vagueness of the term served providers and insurance companies well, because it provided the flexibility needed to make discrete coverage decisions. In the 1960s insurance companies began to question the value of services for which payment was requested, and they began to insert more specific definitions of medical necessity into insurance contracts. These early definitions were brief and continued to rely primarily on the professional judgments of physicians.

Because of the generality of the coverage descriptions for Medicare and Medicaid, states were open to demands by patients and providers for increased coverage. Advocates for the poor or disabled said that states must provide benefits for all “medically necessary” care. Different provider groups interpreted the Medicaid statute’s requirement for “reasonable” coverage as applying to their services in particular.

A sequence of conflicting regulations produced a wide range of state Medicaid definitions of medical necessity, as states tried to respond to the twin pressures of escalating costs and demands from consumers and providers. Most states adopted a definition that applied the typical insurance concept, placing much of the authority for interpretation with doctors: “accepted medical practice or community standards of care; not for the convenience of the patient or provider; not experimental or investigational; and appropriate and effective.” Over the decades that followed, three states (Florida, Minnesota, and South Dakota) introduced the additional criterion of cost-effectiveness into their Medicaid medical necessity definitions, providing administrators with the option of considering cost in coverage decisions. Despite this, costs continued to increase as new services were interpreted as being necessary by providers or consumer advocates.

The private insurance sector began to develop a broader base for decision making about medical necessity in the mid-1970s, by requiring physicians to justify their previously unchallenged decisions. The Medicare program, so dependent on private insurers for its implementation, followed the lead of several prominent private insurer groups by issuing an intermediary letter to its contractors in May 1978, instructing them not to pay routinely for a list of procedures that included ballistocardiogram, icterus index, ligation of internal mammary arteries, and protein-bound iodine.

In the mid-1980s the RAND Corporation, responding to strong interest by both public and private purchasers in a more rigorous analysis of the data on which coverage decisions were based, initiated a series of studies on the appropriateness of various medical procedures. While physicians still made the ultimate judgment of what was appropriate, the standard was no longer the local medical community. Partly because of professional resistance to
the implications of the BAND study, and partly because of the cost and technical difficulty of assessing the appropriateness of hundreds of procedures, many insurance definitions of medical necessity today do not incorporate the concepts of “appropriateness” or “cost-effectiveness.”

The following definition is typical of the approach taken in defining medical necessity in 1995 Blue Cross plans: “Services or supplies which are required for treatment of illness, injury, diseased condition, or impairment and are consistent with the patient’s diagnosis or symptoms; appropriate treatment according to generally accepted standards of medical practice; not provided only as a convenience to the patient or provider; not investigational or unproven; not excessive in scope, duration or intensity; provided at the most appropriate level of service that is safe.” Some specify “of proven value or usefulness” or “not more costly than alternative services,” but attempts to include explicit trade-offs of costs versus benefits or the BAND concept of “appropriateness” in plan definitions have been rare.

Even though insurers have tried to inject the criteria of cost and appropriateness, definitions of medical necessity have changed very little over the past thirty years. The process of making coverage decisions has been broadened, however, to include the payers and purchasers of health insurance, as well as the physicians who provide the care.

Medical Necessity And Health Care Reform

Even though national health insurance legislation failed to pass in 1994, the questions raised during the debate roused the term from dormancy once again. If national legislation were to create a prototype benefit package to be offered to all Americans, what services should be covered, and who should decide? What does it mean for a service to be medically necessary?

As the Clinton administration’s Health Care Task Force developed the benefit plan for its Health Security Act, it became apparent that neither the existing definitions nor the processes by which they were interpreted and applied would work. The Medicare definition was too restrictive and illness oriented. The Medicaid definitions had not succeeded in restraining the growth of state-mandated benefits or in controlling costs or the proliferation of medical technology or providers whose services had to be covered routinely. Private plans defined coverage mainly by long lists of specific exclusions, some of which were longer than the lists of covered services.

The task force suggested the term appropriate, to take into account managed care’s emphasis on health promotion and disease prevention. Medically appropriate would not carry all of the historical baggage of medically necessary and could be reinvented with a new set of criteria by which coverage decisions could be made. The criteria “effective,” “beneficial,” and
“judicious” were designed not only to clarify meaning but also to address the question of who decides and to provide each of the affected parties with a voice. Effective meant that in the reasonable judgment of the provider at the time treatment is administered, sufficient evidence exists to conclude that the treatment’s benefits to the enrollee outweigh its risks. Beneficial meant that in the subjective judgment of the enrollee, the treatment’s benefits outweigh its risks. Judicious meant that in the reasonable judgment of the plan, no other medically appropriate treatment was available that would be as effective and much less costly to the plan.\textsuperscript{11}

The criteria were designed to include consumers, providers, and plan administrators in disputed coverage issues. A detailed process for appeals was described elsewhere in the legislation. The criteria satisfied many of the Clinton administration’s key constituencies. Pro-choice advocates wanted women and their physicians to make the appropriate decisions, particularly about reproductive health services. These criteria would have allowed abortions to be covered as part of pregnancy-related services, because the procedure was effective, beneficial, and judicious for the enrollee. Disabled persons and advocates for the mentally handicapped wanted enrollees (or their representatives) to be able to judge the benefit of any prescribed treatment without undue pressure from medical experts. Physicians and researchers wanted to be able to weigh the risks and benefits of treatments. Insurers wanted to be able to use cost-effectiveness as a basis for selecting among competing treatments of equivalent efficacy.

By the time the plan emerged from the White House drafting process, the criteria for medical appropriateness were deleted from the proposed legislative language, and the terminology medically necessary or appropriate was substituted but left undefined. Presumably, plans could use standard definitions of medical necessity, while the term appropriate was to be left to a National Health Board to define.

Although the Health Security Act did not put forward criteria for defining the terms medical necessity or appropriateness, several other pieces of legislation did. Arguments in the Senate Finance Committee focused primarily on whether or not criteria for medical necessity should be specified in statute or left to be developed by a National Health Board, however that might be constituted.\textsuperscript{12}

In this manner, medical necessity had gone from being an obscure insurance term to being the focus of national debates over who should make the coverage decisions, how those decisions should be made, and at what level of organization or government the authority should reside. By the end of the 1994 legislative session any attempts to define these terms in statute had been severely tested, given the dense nature of medical interest-group politics. The possibility of a new definition of medical necessity and a
National Health Board to apply it died along with the prospects for national health care reform.

**Medical Necessity’s Stakeholders**

The courts, consumers, insurers, and physicians continue to struggle with the issue of what is necessary care.

**The courts.** The courts probably have the strongest stake in resolving definitional issues, because it is to them that irresolvable conflicts are brought. One of the key legal issues related to medical necessity is who has the ultimate authority to pronounce a treatment necessary. The decision in *Doe v. Bolton* is important because it clearly placed the legal right to define the terms in the hands of the prescribing physician, thus reinforcing the authority of the physician.\(^\text{13}\)

Courts have not been consistent in deferring to physician authority, however, and it is likely that the inconsistency correlates with the overall decline of physicians’ power and the increase of managerial authority in the past several decades. Some cases have supported physicians’ decisions; others have given insurers the right to rely on other sources of evidence.\(^\text{14}\)

**Consumers.** Consumers rarely find out about medical necessity until it becomes too personal, too late. The most publicized cases of coverage denial are those such as *Fox v. Health Net*, in which a California jury awarded $89 million in compensatory and punitive damages to the family of a woman who had been denied coverage of a bone marrow transplant for breast cancer because there was little or no evidence of its efficacy.\(^\text{15}\)

**Insurers.** Insurance companies and health plans, both public and private, may prefer to keep their definitions and processes vague, but they face increasing pressure from state legislatures to reveal the criteria they use to make coverage decisions.\(^\text{16}\) The California legislature passed two bills in the 1994 legislative session concerning health plan processes for review of individual cases (S.B. 1832 and A.B. 3244), and a “quality of care” working group consisting of physicians from several of the largest health plans in California recommended to the Department of Corporations in April 1995 that health plans provide enrollees with the specific medical and scientific reasons for denying coverage.\(^\text{17}\) These actions may drive plans to develop more consistent processes and criteria.

There is little consistency now among insurance plans in the ways they define and interpret *medical necessity*. A recent study by the U.S. General Accounting Office (GAO) revealed substantial variation in denial rates for lack of medical necessity. The factors that explained the variation stemmed from varying (and seemingly random) interpretations of national coverage standards, reporting inconsistencies, and differences in the way carriers
treated incomplete claims.\textsuperscript{18}

With the elimination of the congressional Office of Technology Assessment (OTA) in 1995, there may be growing interest among private plans in some consolidation or regionalization of the coverage decision-making process, particularly as it relates to technology assessment. Without any objective or bipartisan assessor, the environment will become even more fragmented, with each health plan doing its own assessments and states performing technology assessments within multiple, overlapping agencies. There is potential for much more effective collaboration among states, between states and the federal government, and between states and the private sector, but collaboration will require resources and commitment.\textsuperscript{19}

**Physicians.** Despite the professional power that physicians still wield over coverage decisions, their authority clearly has been eroded with the ascendancy of managed care and the increasing intrusion into their practices of employer purchasers and insurance administrators.\textsuperscript{20} Part of that erosion has come from the difficulty of translating physicians’ ad hoc decisions into the context of rational decision making in large, complex organizations, and part has come from the lack of consensus on treatment options within the medical community and the lack of clinical evidence about the efficacy of one treatment over another for the same condition.

There also are ethical issues for physicians and other providers in their determination of what is a medically necessary service. As Susan Wolf has written, “The present ambivalence reflects the genuine difficulty of crafting an ethics for physicians in an era of resource constraints and organizational complexity. . . . The question requires us to settle how much we value full information and choice for the patient, physician loyalty to the patient, and patient trust.”\textsuperscript{21}

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**Should Medical Necessity Enter Into Coverage Decisions?**

The term *medical* necessity clearly has lost its definitional focus, and one could conclude that it should be replaced by something else or perhaps by nothing at all. Before we make that conclusion, however, it may be instructive to consider ways to make *medical necessity* a more useful term in the marketplace. If we accept that a placeholder term serves a purpose in coverage decisions, what other criteria and definitions of terms might be useful to consider? The literature on the subject divides into two camps: proposals to clarify the existing definition of medical necessity, and proposals to delete the term completely.

**Proposals to clarify the term.** Some definitions propose an approach that attempts to be neither too broad nor too narrowly tied to a single procedure: “any item or procedure indicated to prevent or cure a condition
that poses serious danger to the physical or mental health of an individual." However, they do not define what is “serious danger” or what is meant by “prevent” or “cure.” Others suggest that we use “covered and noncovered service” or the concept of hierarchy of need, covering what is reasonable care, maintenance, restorative, and so forth.

Mark Pauly advocates a definition that ties medical necessity to the impact of the procedure on the patient. He suggests a method for evaluating costs and benefits in determining whether surgery is necessary. Although his conclusion suggests a certain degree of nihilism—“[k]nowing that we do not know means that we must select public policy based on the fact of ignorance”–he proposes several improvements to the process. These include (1) providing more information to both physicians and patients on the usefulness of surgery; (2) making patients more aware of true costs; and (3) doing more research on patients’ preferences.

Mark Hall and Gerard Anderson, in a review of the courts’ interpretations of medical necessity, approach the definition through a clarification of the process for making coverage decisions. They suggest three contractual mechanisms for coping with the judicial enforcement problems presented by medical necessity or experimental/investigational exclusions in insurance plans: (1) listing of specific exclusions (the problem with exclusions is that courts are inconsistent in interpreting them, and no listing can ever be exhaustive enough); (2) specifying the review criteria (such as using technology assessment criteria for new or experimental procedures); and (3) specifying the technology assessment decisions to be made by specific organizations (obstacles are judicial enforcement and practicality). The second approach is not realistic because most procedures diffuse into practice without clinical trials. It is more realistic to specify the quality of evidence that must be used. Hall and Anderson caution that these options are not sufficient because they do not address the process of making the decisions, which is just as important as the terminology used.

All of these proposals add something to our existing knowledge base. Including the concepts of clinical evidence, impact on the patient, and clarification of the process of making decisions surely would add value to the existing hodgepodge of definitions. The key question is whether these improvements are sufficient to warrant keeping the current terminology.

Proposals to delete the term. In a workshop led by David Eddy in 1994, medical and legal directors of managed care plans scrutinized and defined the terminology related to medical necessity. Out of that workshop, consensus was reached by the group regarding proposed language that eliminated the need for the term medical necessity entirely, but not the need to have clear criteria for coverage and a fair process for resolving disputes. The coverage criteria developed by the group required health plans to cover
interventions if (1) the intervention is used for a medical condition; (2) there is sufficient evidence to draw conclusions about the intervention’s effects on health outcomes; (3) the evidence demonstrates that the intervention can be expected to produce its intended effects on health outcomes; (4) the intervention’s expected beneficial effects on health outcomes outweigh its expected harmful effects; and (5) the intervention is the most cost-effective method available to address the medical condition.

These criteria were followed with definitions of each term and the following caveat: “Nothing in this language prohibits health plans, at their discretion, from covering health interventions that do not meet these criteria.” The group concluded that it was entirely appropriate for health plans to define criteria that limit the services for which they will pay; that the language should be as precise as possible, for legal reasons and so that consumers can understand it better; and that any new criteria should be narrowly defined, because it is the natural tendency of courts and patients to expand the limits of contracts.

**Conclusion**

Let us return to the question that framed this paper: Do we need *medical necessity*? After all of the arguments have been made to fix the old term, there are more compelling reasons to delete it and substitute new language, with new criteria. The old language is laden with legal and administrative meanings that are both contradictory and poorly defined. The health care delivery system has moved away from the traditional insurance model for which *medical necessity* was devised. Increasing litigation and demands on state legislatures to remedy the vagueness and lack of clear process for resolving coverage disputes support a new definition and processes for applying it that are clearer and more collaborative.

Whatever words and definitions are used, several tests must be applied. First, the definition should be thoroughly evaluated by those who use it, are touched by its decisions, or are mandated to carry out the decisions. How would the clarification of terms affect patients? Would they better understand what is covered or not covered by their insurance plans? Would such a definition help them recognize the need for rationing services in a more rational and explicit way? How about physicians? Would this definition help them to base their decisions on a more solid foundation of scientific evidence? Would medical directors of insurers have fewer “bad days” if their decisions were supported by better-informed patients and physicians? Could insurers make the tough decisions about selecting one treatment over another based on the cost or effectiveness of that treatment?

Second, the terminology must be accompanied by an equally rigorous
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and well-defined appeals process. Would such a process mean that the courts would find fewer coverage denial cases on their dockets? And when those cases came forward, would their resolution be easier because the terminology and the process were more clearly defined?

There has been little or no public discussion about the life and death issues affected by the meaning of medical necessity. Some of the discussions about health care reform touched the edges of the issue. As the population ages, as new technology continues to press its findings upon the medical consumer, and as the funding available to pay for wonder drugs and treatments continues to be constrained, even more difficult questions will need to be answered. We must face the ethical, political, economic, and personal meanings wrapped up in medical necessity and clarify both our terminology and the way we use that terminology to make coverage decisions.

NOTES

2. I am grateful to Daniel N. Mendelson, a vice-president at Lewin-VHI, and Robert Alford of the City University of New York for some of these conceptual insights.
4. Optional were home health, private duty nursing, and clinic services; dental care, prescription drugs, and eyeglasses; rehabilitation; physical therapy; and inpatient psychiatric care for persons under age twenty-one. The definition of medical necessity when applied to services for children explicitly recognized developmental issues.
6. Ibid., 1493. The Medicaid statute authorized each state to set its own criteria for services but limited those criteria to standards that were “reasonable and consistent with the objectives of Title XIX (Section 1396a(a)(17)).” The Department of Health, Education, and Welfare’s regulation implementing Section 1396a(a)(17) further defined what was reasonable by stating that the amount, duration, and scope of services covered by the state plans must be sufficient “to reasonably achieve the purpose” of each item of medical care. The regulation further prohibited any standards that arbitrarily limited coverage because of the illness or condition itself.
10. Author’s recollection of private benefits plans designed from 1988 to 1994, while she was a consultant at William M. Mercer, Inc., a benefits consulting firm.
11. The author served as cochairperson of the working group on benefits coverage for the White House Health Care Reform Task Force from February 1993 to May 1993.
Together with cochairperson Robert Valdez, she was responsible for the design of the benefit package in the Health Security Act.


15. No. 219692 (Cal. S.Ct., 28 December 1993). The case was subsequently settled for an undisclosed but substantially smaller sum.

16. In fall 1993, at President Clinton’s first California town hall forum, the first question from the audience was from a young mother whose son had recently died of cancer. Her question was, “Would your health plan have denied him the experimental treatment that might have saved his life?” The president’s answer was, “The health plan would have been able to decide.”

17. The working group focused on experimental procedures and included Wade Aubry (Blue Shield), David Chemof (Blue Cross), Michael Abel (CPMG), Rosalio Lopez (Mullikin), Seymour Levine (Health Source), R. Clifford Ossorio (Health Net), Gene Beed (FHP), and Donald Nielson (Kaiser).


19. D.N. Mendelson, R.G. Abramson, and R.J. Rubin, “State Involvement in Medical Technology Assessment,” Health Affairs (Summer 1995): 83-98. Evidence of interest in collaboration also comes from several recent conferences attended by the author, at which representatives of managed care plans and the OTA discussed the need for collaboration and funding sources for this work.


22. Finley, “State Restrictions on Medicaid Coverage of Medically Necessary Services.”


26. David Eddy was assisted by William Sage and this author in the organization of this workshop of health plan medical director and legal counsel representatives from various Blue Cross plans, under the sponsorship of the National Institute for Health Care Management, in Boulder, Colorado, September 1994.