# Medical Necessity: Making Sense Out of Nonsense

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***Series Editor's Note:*** *Medical necessity, a concept that is hard to define and frequently misunderstood, has become critical to how health care is financed and delivered. Like most physicians, I believe that I have reasonable judgment as to what is medically necessary for my patients. I also understand that at times some of my patients have different ideas regarding what is necessary for their medical care. From the perspective of third party health insurance, however, medical necessity is a specific legal and contractual term that has come to be used to determine what health care benefits are covered, who pays for them, and who makes these decisions. As a result, medical necessity is quickly becoming one of the major health policy issues in the country.*

*To help provide a clearer perspective regarding medical necessity, I have asked Dr. Karen Hein, Executive Officer of the Institute of Medicine and Professor of Pediatrics, Epidemiology, and Social Medicine at the Albert Einstein College of Medicine, to address this issue. Dr. Hein became extensively involved in the area of medical necessity when, as a Robert Wood Johnson Health Policy Fellow in 1993-1994, she served on the Senate Finance Committee, working on legislation relating to health benefits and other issues.*

When today's practicing physicians entered medical school, they undoubtedly thought that they would be learning about how to decide what is best for their patients. Undoubtedly, they anticipated that this judgment call would be based on evidence, experience, and discussion with those most closely involved. What's wrong with this picture? As with the Marcus Welby, MD, caricature of the physician and patient, times have changed. In fact, there are a set of limits, hurdles, and barriers that have become the obstacle course which physicians and their patients must now negotiate. Taken together, these obstacles add up to the catchall phrase *medical necessity*.

This term was originally used to describe services recommended by a physician that would be paid for by an insurer because they were considered essential to improving the health of a patient. During the past few decades, the term has been used more widely in contracts and regulations to apply to groups of people rather than individuals. Medically necessary care has now become the basis for coverage decisions for millions of people, because it is used as the basis of benefits offered by such public programs as Medicaid and Medicare, as well as private insurers.

I am writing this review because, even though physicians might not know it or think about it, the problems related to the use of the term medical necessity affect them greatly. Current controversies surrounding gag rules,[1] drive-through deliveries,[2] mental health parity,[3] denial of emergency services,[4] outpatient mastectomies,[5] appeals of denied services,[6] and coverage of investigational treatments[7] all have their origin in the confusion associated with the use of the term medical necessity. In this review, medical necessity will be defined and explained, with connections made to clinical practice.

## History of the Term *Medical Necessity*

The first and only national meeting on the subject of medical necessity was held in 1995, sponsored by the Agency for Health Care Policy and Research (AHCPR),[8] yet the term has a long and fascinating history. After World War II, as the notion of health insurance gained momentum, insurance companies had to decide how and when to pay physicians for the services they performed. If a physician or hospital said that a service was medically necessary, it was usually paid for without much question. During the 1950s the professional judgment of physicians was the basis for re-

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imbursement, and these determinations were rarely questioned. In 1965, with the passage of Medicare and Medicaid (and with the introduction of new technologies and treatments), patients and health care providers together demanded increased coverage through the new federal programs. States became involved in this dialogue because they had to arbitrate or pay for these services. As the demands increased, so did the cost. The response of individual states was to pass legislation with varying definitions of medical necessity.

During the 1970s the notion of proving the effectiveness of these services and treatments was introduced. Cost effectiveness was added along with other considerations of what did and did not work. By the late 1970s the Medicare program joined with several private insurance companies to put real limits on physician judgment as the only criterion upon which payment would be based. A series of specific procedures were excluded for reimbursement in 1978 because according to the Health Care Financing Administration (HCFA) they were not considered to be effective.

By the early 1980s it was becoming apparent that few studies actually examined the effectiveness of most of the current practices. An awareness of the need for review by groups other than medical practitioners grew from this point on. One of the first studies in the mid-1980s to analyze how coverage decisions are made was provided by the Office of Technology Assessment.[9] For the past decade effectiveness or the results of outcomes research as a basis for decision making has clearly taken hold, although the number of procedures or decisions actually based upon evidence is still relatively small.

## Definitions of Medical Necessity

A report of the Institute of Medicine defines medical necessity as the need for a specific medical service based on clinical expectations that the health benefits of the service will outweigh the health risks.[10] The following public programs have used medical necessity as the basis for defining benefits and therefore coverage policies.

### *Medicare*

Section 1842 of the Social Security Act provides that carriers pay only for services that are covered and that carriers may reject a claim if they determine that the services were not medically necessary. Medicare Part B covers a wide range of health services, such as physician services, outpatient hospital services, the purchase of durable medical equipment, prosthetic devices, and laboratory tests. At the same time, the act limits podiatric, chiropractic, and dental services and specifically excludes some categories of service, such as routine physical checkups and cosmetic surgery. Although carriers make most coverage decisions, HCFA has set national coverage standards for some specific services. Where HCFA has issued a national coverage decision, carriers are expected to enforce it. In the absence of national coverage standards, HCFA has, consistent with Medicare law, given carriers the discretion to develop and apply their own medical policies based on local standards of medical practice.

### *CHAMPUS (Civilian Health and Medical Program of the Uniformed Services)*

Under statutes governing CHAMPUS, payments are prohibited for health care services that are not "medically or psychologically necessary." Coverage for investigational treatments is based upon the following:

1. Whether the drug or device cannot be lawfully marketed without approval of the United States Food and Drug Administration
2. Whether reliable evidence shows that the drug, device, or medical treatment or procedure is the subject of ongoing phase I, II, or III clinical trials
3. Whether reliable evidence shows that the consensus of opinion among experts regarding the drug, device, or medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, or its efficacy as compared with the standard means of treatment or diagnosis.

### *Medicaid*

Within broad national guidelines that the Federal government provides, each of the states (1) establishes its own eligibility standards; (2) determines the type, amount, duration, and scope of services; (3) sets the rate of payment for services; and (4) administers its own program. Thus, Medicaid programs vary considerably from state to state and within each state over time.

**Table 1. Seven Perspectives on Medical Necessity.**

| Perspective | Questions Raised | Current Example of Controversy |
|---|---|---|
| 1. Patient | What do I need to make me better or keep me well? Who decides what is an emergency? | Emergency services |
| 2. Physician | Are there limits to what I can say or recommend regarding the range of treatments or options? How would I determine or advise what is medically necessary in this case? | Who decides what is an emergency? |
| 3. Health plan | What amount of treatment or services are necessary or even appropriate for a healthy outcome for a person who is a member of this plan? | Limits on mental health; drive-through deliveries |
| 4. Employer | How will I know or determine whether my contribution to my employees' health is being well spent in terms of services or treatments that are not excessive or unnecessary, yet are helpful, appropriate, or necessary to improve or maintain the health of my employees? | Denial of services |
| 5. Appeals administrator | How do I interpret a general coverage guideline in a contract to make a decision for an individual case? Is there recent legislation that bears on the decision of whether to cover a service? | Denial of coverage |
| 6. Insurer | By what standards shall I judge whether a given service or treatment should be included as part of a benefit package? What evidence is there and who should say whether the recommended service should actually be paid for under the contract? | Description of benefits |
| 7. Government (state, federal) | Are the decisions being made on an individual or case-by-case basis fair, equitable, uniform, or appropriate uses of public dollars? | Health Care Financing Administration modifications appeals regarding Medicare and Medicaid coverage |

Title XIX of the Social Security Act (Medicaid) requires that, to receive federal matching funds, a state must offer the following certain basic services to the categorically needed populations: inpatient and outpatient hospital services; prenatal care; vaccines for children's program; physician services; nursing facility services for persons aged 21 years or older; family planning services and supplies; rural health clinic services; home health care for persons eligible for skilled nursing services; laboratory and radiography services; pediatric and family nurse practitioner services; nurse-midwife services; certain federally qualified ambulatory and health center services; and early and periodic screening, diagnostic, and treatment services for children up to the age of 21 years. States can also receive federal assistance for funding if they elect to provide other approved optional services.

## Medical Necessity and the Family Physician

In 1997 medical necessity is rarely discussed as a major health policy priority, yet it underlies many recent headline issues producing a flurry of state and federal legislative responses. Family physicians will encounter questions related to medical necessity in all of the ways shown in Table 1.

If a person suspects a heart attack when chest pain suddenly occurs, a common first reaction is to go to a nearby emergency department (perspective 1). Recently the notion of preapproval for reimbursement for emergency services has brought medical necessity problems to a head. Only in retrospect is it clear to the patient (and provider and plan) whether chest pain is myocardial or originates from another source. It is not reasonable or practical to expect patients to know which services or laboratory tests or radiologic examinations are medically necessary during an emergency, and recent rulings in these cases have shifted this triage function (and therefore coverage decision) from the patient to the provider.

The debate about gag rules can be restated as a perspective 2 problem (Table 1). Sixteen states now have laws stating that physicians cannot be limited in describing options for care based upon limits of the patient's insurance coverage or provider contract. In December of 1996 HCFA informed more than 300 Medicare managed care plans that it is a violation of federal law to limit

what treatment options physicians are allowed to discuss with Medicare beneficiaries.[11]

Drive-through deliveries can be seen as a perspective 3 medical necessity problem, in that governments have attempted to define what is medically necessary or appropriate treatment by legislating a particular length of stay. Perspectives 4, 5, and 6 are the basis of a series of disputes about denial of services. Although such treatments or services might be available, if they are not paid for by an insurance plan, they do not exist at all for those who cannot pay for them. Who should say when something should not be paid for? On what basis? What recourse do consumers or health professionals have when a service is denied?

Perspective 6 comes into play for investigational treatments: When does an experimental drug or treatment or device become something that should be offered routinely? Even if experimental, should part of the care or services or device or drug be paid for by the insurer? Who should decide what criteria insurers should use to determine coverage for participation in a clinical trial? Should coverage be based upon whether the rigor of the protocol is scientifically sound enough to give important or reliable results? Is it acceptable to have some plans in which clinical trial treatments are covered and others in which they are not?

The process of challenging denials of coverage is viewed by patients (and providers) as cumbersome, difficult, and possibly unfair. Currently those services that are covered and those that fall outside the interpretation of medically necessary care vary greatly among different plans, and a plethora of laws and lawsuits have addressed one situation at a time rather than at the various levels outlined in this review. Some have proposed that this variability is neither fair nor appropriate when public dollars or programs are involved. Perhaps the President's new Commission on Health Care Quality was partly motivated by a recognition that the problems of medical necessity need national debate, as is implied in perspective 7.

## The Future

Something that started as a simple concept in the 1940s has become incredibly complex and murky at the end of the century. There are currently two camps regarding what to do in the future. The first camp recommends that we address seriously the definition and application of medical necessity from all seven perspectives. The other camp recommends that we continue as we have been, with a series of lawsuits or statutes helping to define for each state or locale or each situation what is currently acceptable, with the likelihood that a great deal of variability will persist from plan to plan, from provider to provider, and from region to region.

There have been attempts to address the variability in coverage decisions based upon different interpretations of medical necessity. Blue Cross/Blue Shield has created review panels to discuss situations that occur commonly in their member plans. The reviews usually focus on coverage of new technologies or participation in treatments as part of clinical investigations. The review panels then make their deliberations available as guidelines for participating plans.

HCFA has an appeal process for individuals who believe that a service or device should be covered, and successful appeals become the basis for new services being included in insurance plans. For example, insurance coverage was recently applied to new urinary incontinence treatments that were determined by AHCPR to be effective.

In the future perhaps review panels might take up broader issues, such as the application of medical necessity to special populations (eg, children). It would be helpful to have principles to apply for extreme situations (eg, extreme measures to preserve life or extreme measures to prevent adverse health outcomes). Because agreement probably occurs more often for extreme situations, it might be best to begin there, leaving the murkier middle issues, such as mental health services, for later consideration.

Ideally, coverage recommendations or guidelines should be useful but flexible. Perhaps a national panel could outline benchmark scenarios to describe standards for insurance plans. Perhaps a useful purpose for a national panel would be conducting surveys and monitoring coverage decisions and lawsuits to establish patterns of coverage, patterns of denials, and the type, number, and outcome of lawsuits.

The debate about medical necessity, because it has not been sufficiently aired, leaves the physician, patient, employer, insurer, health plan administrator, and legislator largely confused.

There might be value, however, in understanding the basis of this confusion and the common thread that unites the seemingly disparate gag rules, drive-through deliveries, denial of services, and investigational treatments. One thing is certain, however. For the rest of this decade and probably well into the next, physicians and patients will be able to make sense of what appears to be disconnected, troublesome events only if they take into account the various perspectives relating to the definition of medical necessity. Jumping over the hurdles means that first the hurdles have to be seen; second, they have to be considered; and third, a decision has to be made about whether to go over or around them. To ignore the terrain would be at the physician's and patient's peril.

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