

## Issues of Medical Necessity: A Medical Director's Guide to Good Faith Adjudication

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### **Abstract**

The term *medical necessity* is difficult to define, a problem for insurers who need to clearly describe what is and is not covered in their contracts with subscribers. An unclear, vague definition of medical necessity leaves insurers vulnerable to litigation by subscribers denied care deemed medically unnecessary. To avoid lawsuits, insurers must make every effort to educate their subscribers about their medical coverage, going beyond merely providing a lengthy subscriber handbook. In decisions on medical necessity, medical directors at insurance companies play a key role. They can bolster the insurer's position in denial-of-care cases in numerous ways, including keeping meticulous records, eliminating unreasonable financial incentives, maintaining a claims denial database, and consulting with other insurers to achieve a consensus on medical necessity.

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*"When all else fails in trying to justify the denial of a health care benefit, use medical necessity—the smart bomb of managed care."*

Linda Peeno, MD

*Testimony before the US House of Representatives,  
Committee on Commerce, Subcommittee on Health and  
Environment (May 30, 1996)*

Although medical necessity is a term often used in contracts between insurers and subscribers, its meaning remains ambiguous.<sup>1</sup> Several courts have turned to *Black's Dictionary of Law* in the search of greater clarity and precision. *Black's* defines necessity as something that is "an absolute physical neces-

sity, an inevitability, or convenient, useful, appropriate, suitable, proper or conducive to the end sought." With this spectrum of meanings available, the courts have consistently construed the meaning in the favor of the insured.<sup>2</sup>

The intent of the medical necessity clause in healthcare contracts is suspect in many quarters. To the extent that it results in denial of inappropriate, not useful, or harmful procedures, the clause is a boon to subscribers. However, if it is used as a means of decreasing medical expenditures, regardless of the merits of the proposed treatment, it is doomed to controversy, contention, litigation, and failure. When a jury is convinced that the insurer has used the medical necessity clause as an excuse to deny benefits, large punitive damages may be awarded to the plaintiff. The case of *Fox v Health Net*, with its \$89 million verdict against the defendants is a case in point.<sup>3</sup> Here the plaintiff alleged that the insurers had denied benefits to save money for the company. During the trial, evidence revealed that the executives in charge of utilization management received bonuses based on dollars saved in medical expenses.

In this article, I explain the problems associated with the current definitions of medical necessity and outline methods for evaluating what is medically necessary in a fair, uniform, and reproducible manner.

### **Current Definitions**

Current corporate definitions of medical necessity are crafted in weak, ambiguous,<sup>4,5</sup> or circular language. A typical corporate definition describes medically necessary as those procedures, treatments, or supplies that are recommended by a licensed physician; appropriate, reasonable, and accepted in the medical community for treating the disease state in question; not experimental or investigational; and not custodial. In addition, the insurer or insurer's review organization typically reserves the right to determine what procedures are medically necessary.

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Problems associated with this definition of medical necessity include ambiguity associated with the definition's wording, use of exclusionary criteria in the definition, failure of the definition to deal effectively with a subscriber's "reasonable expectations," and the court's decreasing belief in the objectivity of the insurance company's adjudication process.

Defining a term with other poorly defined or ambiguous words rarely lends clarity and tends to obfuscate the definition. The above example of a corporate definition does not state who determines what is a reasonable and accepted treatment or in which medical community it would be evaluated. In the case of *Cleland v Bronson Health Care Group*,<sup>6</sup> the court sarcastically pointed out that the term *appropriate* is "one of the most wonderful 'weasel words' in the dictionary and a great aid in the resolution of disputed issues."

### Use of Exclusionary Criteria

In the field of logic, one cannot define a thing by stating what it is not (eg, medically necessary care is not custodial care). Any exclusionary wording in a definition logically invalidates the statement as a definition.<sup>1</sup> Current corporate definitions might be more appropriately called descriptions of what the corporation determines is medically necessary. *Description* is defined as a set of observable facts common to the thing described, this is in contrast to a *definition*, which in the Aristotelian sense, explains the nature or spirit of the thing defined.

In his article on clinical decision making,<sup>7</sup> Eddy proposed that a longer, more comprehensive, and more clearly explained definition of medical necessity would result in a better definition and presumably better patient outcomes. His definitions would be longer, use clear layperson's language, and include a lengthy list of inclusion and exclusion criteria. Although eliminating the fuzzy language of "medical necessity" and adding lengthy exclusionary criteria would be helpful in some determinations, these expanded definitions do not eliminate divergent interpretations of the language, adjust the expectations of the consumer, or bring consensus to legitimate conflicts over the appropriateness of the exclusions. They also cannot anticipate newer therapies or technologies that patients or providers request. As Eddy states,<sup>8</sup> "Perhaps the ultimate limitation is that no language by itself will ever be the final arbiter of any practice; whatever is written at any time will be continually reshaped by expectations, interpretations, actions, and court cases."

### Reasonable Expectations

The court places significant weight on the reasonable expectations of a layperson in the position of a

patient.<sup>8</sup> The court implies that if "reasonable laypersons" could expect a certain medical benefit under their contract, then they may be entitled to it. This expectation principle is used by the courts to justify granting a wide range of benefits to the subscriber that the insurer's policy language appears to exclude. In the *Ponder* case,<sup>9</sup> the insurer denied treatment for temporomandibular joint syndrome, because it was excluded by the contract. The fairness of the contract was questioned, since the purchaser of the insurance did not understand the meaning of the exclusionary criteria in the contract. As the court stated, subscribers "could only discover what they had bought with their premiums as their diseases were diagnosed, and they found out, to their sorrow, the true meaning of those mysterious words in their insurance contracts." In his review of many of these cases, Keeton stated, "An insurer will not be permitted an unconscionable advantage in an insurance transaction even though the policy holder or other person whose interests are affected has manifested fully informed consent."<sup>10</sup>

### Erosion of Trust

The courts no longer implicitly trust the opinions of the insurance company's medical director or the language of the managed care contract. This is not surprising considering the lack of consistency among insurance plans in the way they define and interpret medical necessity. A 1994 survey by the US General Accounting Office revealed "substantial variation" in denial rates for lack of medical necessity.<sup>11</sup>

Historically, the court has been satisfied that medical necessity was met if there had been adherence to the applicable contract provisions in arriving at the benefit coverage determinations. In the parlance of the court, judges traditionally would look no farther than "the four corners of the contract" in adjudicating the case. To the extent that the term *medical necessity* or *medically necessary* was defined in the subscriber contract, adherence to the definitional criteria would be essential to the legal defensibility of the claim decision.<sup>12</sup> If on a procedural level, the defendant could prove that the medical director, rather than an administrator, had made the determination of medical necessity, the decision was again defensible.

The courts now hold that when an insurer reserves the right to decide what is medically necessary, the decision rendered may be considered to be "tainted by self-interest."<sup>13-16</sup> That is, the medical director may have received benefits in accordance with the number of cases he or she denies.<sup>3</sup> Because of this, recent litiga-

tion has demonstrated the court's willingness to go outside the insurer's corporation (eg, to the plaintiff's experts) to seek advice on medical necessity.

The courts have attempted to determine specifically what constitutes the basis for denying the healthcare benefit,<sup>17,18</sup> rather than just establishing the qualifications of the decision maker. This highlights one of the key legal issues related to medical necessity—who has the ultimate authority to pronounce a treatment necessary. The decision in *Doe v Bolton*<sup>19</sup> clearly placed the legal right to define medical necessity in the hands of the prescribing physician. As Justice Blease stated in a subsequent case,<sup>20</sup> “medical necessity is a medical judgment that the measure is reasonable to safeguard or improve the health of the patient.” Unfortunately, the courts have been inconsistent on this issue, resulting in an overall decline in the authority of the prescribing physician and allowing insurers to rely on other sources of information.<sup>21</sup>

### Why The Courts Make Unscientifically Based Decisions

In the absence of suitable definitions of medical necessity, the courts have struggled to define medical necessity themselves.<sup>14,15,22</sup> These determinations, known as “judge-made law,” have included the authorization of benefits such as cosmetic surgery, thermography,<sup>23</sup> an artificial heart,<sup>24</sup> chelation therapy,<sup>25</sup> and sex-change operations.<sup>26</sup> Why would the courts certify such obviously unproved procedures as being medically necessary?

In an analysis of 17 cases in which courts ordered insurers to cover unproved medical technologies, Ferguson et al<sup>27</sup> identified three reasons for this apparent deficit: (1) legal principles; (2) the reluctance of the courts to use published scientific data as evidence; and (3) the common use of adversarial expert witnesses with potential conflicts of interest.

*Legal Principles.* The legal principle governing the interpretation of a contract states that ambiguities in the contract should be construed in favor of the insured. Unlike other business contracts,<sup>28</sup> insurance contracts must be interpreted most strongly against the insurer, on the grounds that a person has little choice but to sign the contract or forgo the service. Although there has been a significant amount of this judge-made law, recent case law has witnessed an opposing trend. In *Blue Cross/Blue Shield of Virginia v Keller*, the court allowed “as we frequently have stated, a court must adhere to the terms of a contract of insurance as written, if they are plain, clear and not in violation of law or inconsistent with public policy.

It is not our function to ‘make a new contract’ for the parties different from that plainly intended and thus create a liability not assumed by the insurer.”<sup>29</sup> This tendency has been noted in other cases as well.<sup>30-32</sup>

*Use of Medical Literature.* Although physicians are comfortable making decisions about the effectiveness of medical procedures based on their review and understanding of the medical literature, the courts have not demonstrated the same capacity. Judges are reluctant to use scientific information as medical scientists do because they lack the sophistication to evaluate the literature critically.<sup>33</sup> Additionally, the hearsay rule does not permit admission as evidence of out-of-court statements that cannot be cross-examined.

*Preference for Live Witnesses.* The courts prefer the testimony of live experts to learned medical treatises.<sup>34,35</sup> Many courts give more credence to the medical judgment of the attending physician<sup>13,35,36</sup> than to the clarity of the contractual definition, the relevant medical literature, or the objectivity of the insurer's medical director. The court's preference for live testimony extends even to the medical expert who has a vested interest in the coverage of the procedure in question.<sup>37</sup> Often healthcare providers have the strongest financial interest in having their procedure covered and therefore willingly testify in court to its effectiveness, citing their unique knowledge of both the therapy and the patient.

Noting this, defense attorneys have contended that the attending physician may have pecuniary and professional interests in performing the procedure and, therefore, may not be as objective as some assume. For example, a course of high-dose chemotherapy and stem cell support (bone marrow transplant) may cost upward of \$200,000. A significant percentage of that money goes to the attending physician. The attending physician also may derive income from drug developers and prestige in the medical community for having done the research. These considerations may decrease the objectivity of the attending physician in a particular case. This emphasizes the need for objective medical consultants in high-profile claims determinations. Although the courts can hire their own expert witnesses to supplement those of the plaintiff and defendant, they seldom exercise this right.<sup>38</sup>

### Punitive Damages

The insurance companies' callousness and disregard for the health and welfare of their subscribers often encourages juries to award large punitive damages to plaintiffs.<sup>3</sup> Medical directors, through their

manifest concern for the subscriber and careful decision-making, may be able to spare the insurer the costs of punitive damages, even if their judgment is questioned.

### Can the Definitions Be Improved?

A procedural approach to defining medical necessity may effectively bolster the insurance company's contractual definition, especially when this definition is contested in court. The solution lies in the hands of the medical director. His or her responsibility is to manage the process of claims adjudication for medical necessity. The medical director must ensure, on the one hand, that subscribers receive everything they paid for and are not subjected to ineffective or harmful treatment and, on the other hand, that subscribers' premium dollars are not wasted on non-medical, ineffective, or harmful practices. Furthermore, the medical director must ensure that the process for making these decisions is fair, reproducible, and based on the best medical information available. This is called a procedural definition of medical necessity.

The best solution, therefore, lies not only in improving a contractual definition that contains exhaustive exclusionary criteria but also in defining a process for determining medical necessity. The goal of this process is to improve the health of subscribers and protect them from harm through rigorous, scientifically sound, and manifestly fair methods. This process entails the following procedures:<sup>39</sup>

*Firmly establish the intent of the medical necessity clause in all documentation.* The intent of a medical necessity clause is to protect subscribers from irregular, dangerous, or unnecessary procedures. It is in insurers' best interests to make subscribers' best interests their first priority. This intent of the clause should be clearly stated in the contract, the subscribers' handbook, and any other communications between the subscriber and the insurer.

*Implement medical oversight.* The medical director, a licensed physician, should review and approve all benefit denials.<sup>39</sup>

*Eliminate perverse incentives.* The compensation of the medical director and the utilization staff should not depend on the number of dollars saved through claims denials but on their adherence to the tenets and goals of the review process.

*Be aware of high-profile cases.* The medical director, risk manager, and corporate counsel should be aware of all high-profile cases (ie, those most likely to be legally contested or result in unfavorable media coverage, such as expensive, high-risk procedures; bone marrow transplant; neurosurgeries; and treatment of infants in pediatric intensive care units or oncology wards). These cases, which have a high potential for grievances and

appeals, are more intensely scrutinized by subscribers, regulators, and the courts. They should therefore generate a commensurate amount of investigation and consideration by the medical director and others involved in the case.

*Consult objective specialists.* Cases that fall outside the medical director's area of expertise should be reviewed by independent, external, unbiased medical consultants. An unbiased consultant is one who does not derive a significant amount of income from expert testimony.

*Request and review the medical record.* The medical director must be alert to extenuating circumstances or clinical issues that may mitigate the claims denial. Medical directors should record the time, date, and findings from the chart review and any subsequent interviews or examinations in their notes.

*Speak to both the patient's attending physician and the specialist.* To obtain a complete clinical picture, the medical director must speak with all physicians involved in the patient's care. Because of the narrow focus of the clinician in his medical charting, the patient's record does not always contain enough information to make an informed decision. The medical director should record the time, date, and content of the interview. As noted above, the courts give great credence and probative value to the testimony of the treating physician.<sup>40</sup> A common complaint is that insurers and their medical directors make decisions about patients without ever having seen or examined them. Having the insured examined by an independent, objective, third-party physician before issuing a denial in cases in which the requests for treatment or care exceed expectations of the insurance company and its medical director is prudent.

*Document all decisions.* Denials associated with cases in which requests for care exceed expectations should be fully documented. These documents should include both the cause of the denial (eg, not medically necessary) and the reasons for it. Any literature or expert testimony relied on in making the decision should be included in the file. Malpractice experience has taught physicians the importance of proper clinical documentation; the same care should be exercised in administrative medicine. A comprehensive set of notes making the logical case for benefits denial, complete with attachments that provide all information used to make the decision, can have a chilling effect on a plaintiff's resolve to litigate. Keep in mind that the plaintiff and his attorney will produce as much evidence as necessary to prove their alternative point of view. Without clear and convincing documentation of your own, your opinions will appear arbitrary and capricious.

*Achieve consensus among insurers.* The courts attempt to foster uniformity in decision making and future

defensibility in adjudicating claims denial cases. To that end, the courts may consider a company's past practices in benefit determinations in similar cases. They may also consider the decisions of the insurer in the case being litigated and those of other insurers in the same type of case. Therefore, the medical director should poll other insurers in the area to determine how they define medical necessity. A consensus among insurers regarding issues of medical necessity is advocated for this reason. Flaunting established convention without good reason is inadvisable.

*Maintain a denial database.* When denying claims, the medical director should review past decisions regarding the type of treatment under consideration. Lack of consistency in decision making opens the insurer to criticisms of arbitrary and capricious conduct. Insurers should maintain a database of prior decisions on medical necessity so these decisions can be reviewed and used to guide research and investigation into future claims issues.

*Address subscribers' expectations.* Insurers must address the reasonable expectations of their subscribers. Although a full explanation in the subscribers' manual is a good start, most subscribers do not read this document. Timely information about benefits and education about disease states is useful to subscribers. Case management and disease management programs are excellent venues for educating subscribers and their family members or caregivers. Educating subscribers about what to expect during procedures, surgeries, hospitalizations, and rehabilitation is good patient care. Informing them about their benefits, including what is and is not covered, avoids surprises on the subscribers' part and may prevent future litigation.

*Regularly review utilization review procedures, including software edits in the claims system that defines covered benefits.* Inaccuracies in the claims system may lead to unwarranted denials.

### Conclusion

A comprehensive definition of medical necessity, while highly desirable, no longer satisfies subscribers or protects insurers against litigation. In determining medical necessity, insurers should strive to provide subscribers with the safest, most useful care needed. Insurers' attention to this process, rather than their contractual definition alone, will improve subscriber satisfaction and decrease liability. Educating subscribers about the contract's benefits will temper their expectations when benefits are required. The medical director should control the process, consult experts liberally, and document extensively.

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