

*Should health plans cover “necessary” care, or the specific care that someone has bought?*

# The Futility of Medical Necessity

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**T**HE PAST FEW YEARS IN HEALTH CARE have been a story of extraordinary turbulence. After decades of uncontrolled cost escalation, the businesses and governments that directly pay for most health care finally mandated a fiscal restraint that, in the early 1990s, launched in earnest the upheaval known as “managed care.” One major result has been the replacement of such values as, “If it might help and won’t hurt, do it,” and, “Too much is better than too little,” with conservative edicts such as, “If you can’t demonstrate its value, don’t do it.”

Virtually everyone can claim disenchantment with the upheaval in health care. Patients who expect their health plans to cover the latest tests and treatments are angry when their plans’ administrators refuse. Physicians must routinely justify their every medical move to outside parties and must be vigilant for the economic as well as the medical wisdom of their care. Employers, tantalized for a brief period by health plan premiums that were level if not actually declining, are now dismayed by the re-emergence of double-digit health care inflation. And health plans struggle to balance enrollees’ demands for the latest and greatest medical innovations against purchasers’ demands for controlled spending and lower premium prices, as well as societal demands that the plans promote the best interests of the broader population.

This single article cannot begin to explore the causal latticework behind all of the disenchanting changes in the American health care system. But we can examine one major culprit: the notion of medical necessity. “Medical necessity” defines patients’ entitlements under various health plans: they can rightly expect their plans to cover

everything that is necessary. It also marks the limits beyond which patient expectations should not tread. Medical necessity provides the conceptual fulcrum of virtually all health plan contracts, seemingly offering a bright promise of excellent-but-not-excessive medicine. Unfortunately, the reality could hardly be further from the promise.

## HISTORY OF MEDICAL NECESSITY

As health insurance emerged in the 1930s and became a standard workplace benefit in the ‘40s and ‘50s, insurers nearly always deferred to physicians’ judgments about what care a patient should have. Insurers existed to ensure that patients could pay hospitals and physicians, and there was little basis or reason to challenge professional opinions about complex scientific matters.

But as health care costs began spiraling upward, payers realized that care was sometimes excessive, experimental, or merely convenient. In the 1960s, providers tried to limit their coverage to just the “medically necessary” services. Even then, health plans tended to operationalize medical necessity by deferring to the collective judgments of the medical profession. After all, medicine is extraordinarily complex and, prior to the recent emergence of systematic clinical guidelines, it was impossible to specify with any detail which interventions should be provided under what conditions.

More recently, as research showed that medical practices for various conditions vary widely and often inexplicably and as costs continued to soar, health plans began to assert far greater control over their expenditures. Contracts ostensibly still base coverage decisions on physician-determined medical necessity (albeit supplemented by more, and more explicit, exclusions), but most health plans operationalize necessity via guidelines that tell physicians, rather than ask them, what is necessary and what is not. Many plans also have added specific procedures for determining the necessity of new technologies and innovative procedures.

Although most health plans implicitly acknowledge

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that they owe their beneficiaries necessary care, it is not at all clear what “medical necessity” is. The term is notoriously difficult, if not impossible, to define. At one extreme, an intervention could be understood as necessary only if it is essential to reach a goal of improving or curing a disease. In principle, that minimalist definition could preempt many interventions currently deemed standard – even such mundane things as anesthesia for painful outpatient procedures. In contrast, Medicare defines “reasonable and necessary” intervention as that which is “safe and effective, not experimental, and appropriate” as described in the Food, Drug, and Cosmetic Act of 1938. That broader approach dubs an intervention necessary if it “works.” In another common definition, medical necessity means, “sufficiently accepted within the medical community to be covered as acceptable medical care.” Middle-ground definitions have begun to add the caveat that a service is only necessary if there is no comparable service that is more conservative or less costly.

#### MEDICALLY NECESSARY?

Some medical plans could claim that physical therapy is unnecessary.



JEFF CADGE/IMAGE BANK

## PROBLEMS OF MEDICAL NECESSITY

Using the concept of medical necessity as the contractual cornerstone of health care benefits creates problems that go far deeper than the familiar complaints about outsiders’ meddling in medicine. Among those problems are medical necessity’s legal vagueness, clinical artificiality, and its unreliability and restrictiveness for consumers.

**Legal vagueness** From health plans’ perspective, perhaps the biggest drawback to the medical necessity criterion is that its vagueness renders benefits denials difficult to defend in court. As a general principle of contract law, courts routinely construe ambiguities against contracts’ drafters in accordance with the doctrine of *contra proferentem*. The doctrine is based on the fairness principle that, because the party that authored the agreement had the opportunity to make the wording clear, its failure to do so should not work against the party that lacked that opportunity. Given the obvious vagueness of the medical necessity concept, courts have often used

*contra proferentem* as justification for overturning health plan administrators’ denials of benefits. So long as health plans invoke the ambiguous concept of medical necessity to guide benefit decisions, and so long as courts honor *contra proferentem*, plans can usually expect to lose when their denials are challenged. A substantial body of case law has overturned plans’ benefit denials on that very ground.

On the other hand, the courts are more willing to uphold benefit denials when the contract terms are clear. For example, in the 1993 case of *Loyola University of Chicago v. Humana Ins. Co.*, surgeons performing a health plan-covered coronary bypass surgery responded to an intra-operative emergency by implanting an artificial heart as a bridge to a human heart transplant that doctors performed a month later. The insurer refused reimbursement for the artificial heart because it was experimental, and for the human heart transplant because the patient failed to secure preauthorization as required. The federal Seventh Circuit Court of Appeal upheld that refusal, declaring that “Loyola and [the patient] were certainly free to attempt these life-saving procedures, but Humana is not required to pay for them.” The court continued:

As the plan unambiguously states, no benefits are payable without prior approval. It is undisputed that necessary records on [the patient’s] condition were not sent by Loyola until after the heart transplant and that the records were not received by Humana until after [the patient’s] death. ... Although it seems callous for Humana to deny coverage for a life-saving procedure

and thereafter deny all subsequent hospital expenses—in essence saying to [the patient], ‘we will not cover you because you should be dead’—Humana’s humanity is not the issue here. This is a contract case and the language of the benefit plan controls. (996 F.2d 895, 903 (7th Cir. 1993))

Thus, so long as courts balk when the only basis for benefits denial is a fuzzy claim that “we consider this to be medically unnecessary” and, reciprocally, so long as they are quite willing to uphold clear contracts, a health plan that wants to enforce limits on its expenditures effectively should abjure the medical necessity tradition in favor of considerably more explicit contract terms.

**Clinical artificiality** The ill fit between “necessity” and ordinary medical care is immediately obvious in the question facetiously bandied about when health plans first considered what to do about a recently approved drug for male impotence: How often per month (per week? per day?) is drug-assisted sexual intercourse “medically necessary”?

As typified by that case, most medical decisions do not post clear choices of life versus death, nor juxtapose complete cures against pure quackery. Rather, the daily stuff of medicine is a continuum requiring a constant weighing of uncertainties and values. One antibiotic regimen may be medically comparable to and much less expensive than another, but with slightly higher risk of damage to hearing or to organs like kidneys or liver. For a patient needing hip replacement, one prosthetic joint may be longer-lasting but far costlier than an alternative. Of two equally effective drugs for hypertension, the costlier one may be more palatable because it has fewer side effects and a convenient once-a-day dosage.

Across such choices, it is artificially precise to say that one option is “necessary” — with the usual connotation of “essential” or “indispensable” — while the other is “unnecessary” — with the usual connotation of “superfluous” or “pointless.” Various options have merits, and often no single approach is the clear, “correct” choice. A given option might be better described as “a good idea in this case,” “reasonable, given the cost of the alternative,” “probably better than the alternative, given a specific goal,” “about as good as anything else,” or “not quite ideal, but still acceptable.”

In many cases, the real question is whether a particular medical risk or monetary cost is worth incurring in order to achieve a desired level of symptomatic relief or functional improvement, or to reduce the risk of an adverse outcome or a missed diagnosis. A huge array of treatments fits that description: more or less worthwhile, but the patient will not die without it and other alternatives (that might have some drawbacks) exist.

More broadly, concepts like necessity, appropriateness, and effectiveness can only be defined relative to a goal. For example, antibiotics are not clinically effective for all illnesses; they are effective against bacteria but, barring placebo effect, they are ineffective against viruses. Hence, it

makes no sense for a physician to prescribe antibiotics to eradicate a viral infection. However, if the goal is to placate a relentlessly demanding patient who insists on antibiotics for his viral infection, the prescription may indeed serve that latter aim — which is probably why so many physicians write so many antibiotic prescriptions for viral illnesses.

Choices in this realm require a level of clinical complexity that is not reflected in simplistic notions like necessity, and that should not be hidden under blanket categories connoting a façade of precision. It would be far better to acknowledge that, across a broad spectrum of such choices and trade-offs, it is legitimate for people to come to different conclusions about what sort of price is worth paying, medically and financially, to achieve specific goals. To presume that a medical intervention is objectively either necessary or unnecessary belies the legitimacy of such variation in human goals and values.

**Unreliability and restrictiveness** Patients can be harmed in several ways when benefits are allocated according to medical necessity. In the first place, the concept invites enrollees to entertain high, uniform expectations. So long as virtually every plan implicitly appears to promise all “necessary” care within the covered categories, and so long as a person assumes (as many laymen do) that medicine is highly scientific and precise, then it is reasonable for health plan subscribers to expect that all plans based on medical necessity will provide the same benefits, aside from whatever explicit exceptions may differentiate them. And if, beyond this, subscribers invoke the most common conception of medical necessity — the definition that only requires an intervention to be safe, effective, and appropriate in order to be “necessary” — then enrollees will rightly believe they are entitled to receive “everything that works” regardless of the price of their plan. Indeed, the very notion of medical necessity implies a thoroughly scientific, medicine-based evaluation, to which economic and normative considerations are irrelevant.

However, as noted above, “medical necessity” can be defined very differently from one health plan to the next, ranging narrowly from only those interventions that will diagnose or cure disease to broad versions encompassing virtually everything that works. Even a uniform definition would not solve the problem. The federal Medicare program for the elderly and disabled, for example, ostensibly provides a uniform set of benefits to all enrollees, even though various insurers act as the plan’s fiscal intermediaries. Yet in a study conducted by the General Accounting Office, Medicare payment for a chest x-ray was 451 times more likely to be denied in Illinois than in South Carolina; payment for a physician office visit was almost 10 times more likely to be denied in Wisconsin than in California; and payment for real-time echocardiography was nearly 100 times more likely to be denied by Transamerica Occidental than by Blue Shield of California.

Just as the definition and practical implementation of medical necessity can vary widely from one plan or

geographic region to another, so can implementation change quickly and quietly within a plan. One area in which an erosion of benefits is particularly disturbing concerns interventions that are intended to improve quality of life, as distinct from more dramatic life-and-death treatments. For example, rehabilitation to improve function or enhance comfort, which was once deemed standard, is becoming scarcer. Thus, patients with stroke may be discharged to nursing homes rather than to rehabilitation facilities. A plan may decide that epidural anesthesia is unnecessary for normal vaginal childbirth because, after all, the pain is only transient. In some cases, entire medical disciplines such as dermatology, ophthalmology, reconstructive plastic surgery, and end-of-life care are coming under economic pressure because they focus mainly on quality of life.

As a health plan's guidelines and specific benefits shift underneath the vaguely worded contract, the result can be a steady erosion of that plan's actual coverage. A subscriber cannot know upfront precisely what he has purchased in a health plan, nor can he later be sure that he owns what he originally thought he bought. The plan may cover much less than he thinks if administrators flesh out the slippery "necessity" concept differently than he expects. Where necessity is defined according to physician acceptance, the iteration of what "works" can change as fleetingly as the fashions of consensus. And because the vague concept of "necessary" does not fit quality of life-oriented interventions very well, it is easy for health plans to dub those interventions discretionary and unnecessary, and therefore eminently eliminable.

It is worth noting that, when health plans shrink their iteration of necessary services, patients often do not enjoy financial savings. Everyone but the patient seems to benefit as health plans, employers, and governments pocket the savings while patients endure greater discomfort, reduced function, or even a diminished chance for survival.

Unfortunately, so long as the deleted interventions are dubbed "unnecessary," patients ostensibly are not being deprived of anything important and the underlying, value-laden trade-offs remain unrecognized. Even where the benefit cuts serve mainly to avert cost increases, patients rarely have the opportunity to participate in decisions about which of the benefits financed by their own money should be cut, and which retained.

### NECESSITY VERSUS CHOICE

Thus, in a sense, the notion of necessity preempts consumer choice. "Necessary" is an imperative; as noted by an Ohio appellate court borrowing from Webster's dictionary, it is synonymous with "essential, inevitable, inescapable, predetermined, compulsory, absolutely needed, required." The general tenor is that something necessary is something indispensable. In medicine, people other than the patient make most of the important decisions regarding what should be covered and what should not. Up to a point, that reasoning is valid. If the fundamental

objectives of health care are to save lives and preserve capacities for function, medical science has much to say regarding which sorts of care are essential, which are marginal, and which are actually harmful toward those goals. But that analysis is hardly the final word. Necessity and effectiveness, as noted, can only be defined relative to a goal. And the principle of informed consent holds that the patient, not the health plan or even the physician, should ordinarily choose the goals and, within certain parameters, also the means of treatment.

People can legitimately differ on the value they place on the various goals that health care can achieve, from reducing their risk of undetected illness, to increasing their comfort during medical procedures, to improving their ability to function in the daily tasks of life, to making extra-sure that an infection is eliminated a little sooner rather than a little later. By the same token, there are legitimate choices between health care and the world outside. Elsewhere in life, people forgo many products and services that they deem not to be worth the cost, even though the items may be clearly useful in their own right. People buy cheaper, older cars that are less crash-worthy than new ones, and many buy a good restaurant meal before boosting their retirement fund. On the whole, the freedom to make such choices is vital; it is the currency of human autonomy that permits each individual to be the kind of person he wants to be and to live as he sees fit. Only if people have the opportunity to choose among health plans and levels of care can they meaningfully act on the values of choice in the important setting of personal health care.

Calling an intervention "necessary" usually means the health plan must cover it and that subscribers must pay for it in the price of the premium. When necessity is defined as "everything that works," people can be forced to pay for care that many might deem excessive. Combine those features with the virtual impossibility of knowing in advance what a necessity-based plan includes, and it becomes impossible to select a plan on the basis of what it does and does not cover. Consumers have little or no control over what they buy.

### GUIDELINES-BASED CONTRACTING

To avoid the above problems for doctors, patients, and health care plans themselves, plans should jettison the notion of medical necessity and the vague promises of providing "all the care you need." Instead, plans should turn to guidelines-based contracting: they should lay open to consumers the clinical guidelines by which they make benefit determinations, explain the procedures by which the guidelines will change over time, describe the procedures they use to adjudicate disputes and resolve ambiguous cases, and then make those guidelines and procedures the explicit basis on which they contract with enrollees. Put simply, plans should say to consumers, "If you buy this plan, here is what you will receive."

To be sure, the sheer complexity of medicine and of health care systems probably precludes a thoroughgoing "meeting of the minds" between enrollees and health plans.

Still, guidelines-based contracts can meet the important elements of enforceable contracting better than necessity-based contracts. Guidelines-based contracting need not require that prospective subscribers understand and affirm every clause of every guideline in order for the contract to be valid. Such detailed comprehension is not required for valid contracting in health care any more than a contract to buy an automobile requires the buyer to understand how the car is put together. Rather, the central elements of open health care contracting would require each plan to acknowledge publicly that the care it covers is limited, and to provide information about how the plan chooses those limits. The plan could present an outline of its general resource philosophy and procedures — perhaps supplemented by case-illustrations showing how the plan implements that philosophy — and then provide information about how the consumer could inspect the complete, detailed guidelines. A website might serve the latter purpose well.

Only when health care is built on such an explicit basis can consumers know what they are purchasing and detect when their benefits have eroded. And only when health plans craft explicit policies with enforceable limits will they be able to plan optimal use of limited resources for a broad population. Additionally, only when guidelines are open can they be exposed to examination, critique, and improvement from physicians and the public alike.

### CAVEATS AND CHALLENGES

Even if guidelines-based contracting might be an ideal, some important challenges remain. Thus far, health plans have shown little inclination toward such openness. In addition, a potentially significant barrier to opening guidelines to inspection is the fact that some guidelines are commercially proprietary, requiring the plans that use them to not disclose their contents. If guidelines-based contracting is to become the norm, some resolution — perhaps a broad-based buy-out — must be found for that problem. Indeed, there is already movement toward less proprietary secrecy for clinical guidelines. New Jersey, for instance, inhibits such secrecy by requiring that health plans permit their participating providers “an opportunity to review and comment on all medical and surgical ... protocols ... of the carrier.” The state of Washington has a similar provision. In addition, some health plans now encourage providers to pattern their practice on guidelines that are already published in books and on the Internet. Beyond that, health plans in particular geographic regions such as Minnesota and New Mexico have begun to agree on uniform treatment guidelines for common conditions, a step that requires those guidelines to be open for physicians to follow.

More broadly, a huge variety of arrangements has come and gone during the tumultuous evolution in health care. Plans and providers are learning, from encounters with each other, with patients, with medical providers, and with their accountants, that some of the arrangements they have tried do not work very well. Intensive utilization manage-

ment and gatekeeping systems are giving way to broader profiling of providers and practices; incentives have gone from crude cash rewards for cost-cuts to more sophisticated mixes rewarding productivity, quality, and other improved practices along with cost-consciousness.

Plans are also beginning to learn, through harsh experience with the courts, that there is little point in continuing to rely on vague language they know will be construed against them. They are learning that the more specifically they write their exclusions and other provisions, the more likely they are to be enforced. Reciprocally, concealment of important provisions is beginning to cause major trouble. The incentive schemes by which plans encourage providers to cut costs are prompting judicial scrutiny, and some courts have decided that health plans and physicians alike may have breached fiduciary duties by failing to disclose such incentives.

### CONCLUSION

Discarding the concept of medical necessity in favor of guidelines-based contracting will not heal all that ails our health care system. However, it is a critical step. So long as health plans, including commercial insurers and HMOs, self-insured plans, and even government programs, give only vague promises in exchange for large amounts of money, so long as the plans commonly keep secret the guidelines by which they award benefits, so long as the actual benefits people receive within a particular plan keep fluctuating under the rubric that “we have decided that service is (no longer) necessary,” and so long as different plans make widely differing judgments under the very same benefits language, it will be difficult for us as a nation, and for health plans individually, to use resources wisely and to serve populations well while treating individual patients fairly.

Conversely, guidelines-based contracting, with its greater clarity and openness, can permit much greater opportunity for patients to choose the resource-level they want to purchase for their health care and to hold health plans to account when they do not deliver. It can permit health plans to circumscribe much more clearly what they do and do not cover, and enforce those limits in an above-board spirit of fairness to all. With greater predictability in their obligations and expenses, plans can strategize more effectively for meeting diverse needs of a population within a defined budget.

For physicians and patients, the enhanced openness and clarity of guidelines-based contracting could relieve much of the rancor, dread, and gamesmanship that currently beleaguer medicine. If physicians know — rather than have to guess or argue — about what a plan covers, if the “sunshine” of open guidelines prompts plans to enforce their resource limits more evenly than they do at present, and if patient can voluntarily and knowingly agree to the parameters of a plan (even if it does not cover every intervention that might ideally benefit the patient), the change would be a great improvement over “medical necessity.” **R**