

Bernard J. Mansheim, MD
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The mission at Coventry Health Care is to provide high quality, affordable health care to our several million members.

There is no dollar limit to the coverage we offer, whether a member has Gaucher’s disease and needs Cerezyme at a cost of \$200,000/yr, or a bone marrow transplantation and its potential complications that could exceed \$1 million .

These comprehensive health benefits are provided for a fixed premium, paid to us by an employer or by the government for Medicaid and Medicare enrollees. The vast majority of our membership is fully insured- meaning that if health expenses exceed the premium revenue, it is our financial risk.

How we manage this fixed premium is the key to our success or failure. It is done in three ways. First, we keep our administrative costs as low as possible. The opportunity here is relatively small, since at peak efficiency these costs cannot be managed much below 10% of total premium. By far the highest premium component is medical cost, which comprises well over 80-85% of the total premium dollar.

The challenge we face every day is how to manage health care cost for our members, without compromising the quality of care they receive.

The total cost of health care services is made up of the mathematical product of two components: unit price and volume of service. Despite its obvious importance, I will not discuss the unit price component today as it has no immediate relevance to this presentation. My comments will focus on management of the volume- and associated intensity of health services, an activity known as utilization management.

How does all this relate to the impressive array of topics discussed over the past two days? Though perhaps not obvious, all the topics discussed in this forum have immediate relevance to our ability to provide comprehensive, affordable health care. Let me explain.

For us, the first order of business is to offer health care coverage. To this day, like most health insurance carriers, our Coverage Policies state that we cover “Only services that are Medically Necessary”. The implication from this simple statement is that we cover ALL medical services that are medically necessary. Parenthetically, it will not be possible in the future to cover ALL medically necessary services. The issue of rationing must rise to the level of discussion- but that is a subject for another day.

Suffice to say, except for a relatively short list of explicitly stated exclusions, such as “services for work-related injuries” or “food and food supplements”, our coverage under this umbrella is extremely broad.

Our foremost challenge is to interpret the phrase “medical necessity”, because how we define it dictates what we cover, or pay for. Though it has no useful literal meaning, it is a commonly used phrase that begs for definition.

Once, but no longer, it may have meant “anything a doctor wants to do”. Today it means different things to different people. Since there is no universal definition, and in order to clarify our contractual responsibility, we must define what we mean..

Our definition of medical necessity includes 7 components as listed on this slide (Slide 1)

Health services must be:

1. Medically appropriate, meaning that expected benefits materially exceed expected health risks
2. Done in a manner consistent with scientifically-based guidelines
3. Not experimental ...and so forth...
4. Performed to improve health, that is not for cosmetic purposes
5. Rendered in the most cost-efficient manner and setting
6. Done in a manner consistent with the diagnosis
7. Done for reasons other than comfort or convenience

My focus is on the first three points. First, I need to define the word “Experimental”. Once again, it means different thing to different people, so it requires a contractual definition, as seen on Slide 2.

An experimental health service is one or more of the following- the first 3 criteria are straightforward. The 4th: “any health...” is less clear, but no less essential.

1. Any drug not approved by FDA
2. Any service that is subject to IRB approval
3. Any service that is part of a Phase 1, 2 or 3 Clinical Trial

4. Any health product or service that is considered not to have demonstrated value based on clinical evidence reported by peer-review medical literature and by generally recognized academic experts.

For clarity’s sake, we explicitly state that the word experimental is synonymous with the words investigational and unproven.

Having laid this groundwork, I will point out the complexity that arises in our very real world.

First, I must comment on the unavoidable ambiguity of language. Under medical necessity, we use phrases like “benefits materially exceed health care risks”. One could rightfully ask “What does materially mean?”. In fact, any effort to be more precise leads only to more questions.

I’m quite sure we cannot escape with a paraphrase of the comment Supreme Court Justice Potter Stewart made in 1964 regarding the definition of pornography: “Even if we can’t define it, we know it when we see it”. And to avoid the issue means, at the very least, unhappy members and doctors, and ultimately painful and protracted legal wrangling

Thus, we have tried to be clear about what we mean. What we mean is that we will pay for health services that are considered “standard of care”.

The legal profession has defined standard of care for us (slide 3) as follows:

“The average degree of skill, care and diligence exercised by members of the same profession practicing in the same or a similar locality in light of the present state of medical and surgical science”.

I can assure you that such a definition sheds no light on the problem. We are still left with ambiguity. But, undaunted, our quest continues. To make an attempt at clarity, we state that the synonyms “experimental, investigational and unproven” are the converse of “standard of care”. Thus, a service cannot- by definition- be experimental AND be the standard of care.

Despite this declaration, it is not unusual, when we send an appeal of a denial to an outside expert for review, to get back a comment like the following (Slide 4):

“this malignancy (NK/T lymphoma)is uncommon enough to limit the amount of information available as to make this treatment statistically superior to other forms of therapy. However, this is the current standard of care.

There is no question that this approach could also be considered investigational because of the lack of significant clinical information. However, these terms- standard of care and investigational or unproven- do not have to be incompatible or inconsistent”.

Or take the case of a 60 year old woman with high risk myelodysplastic syndrome, proposed for an allogeneic stem cell transplant. According to the National Cancer Institute cancer treatment guidelines, known as PDQ, patients in her disease category have a mean life expectancy of less than six months, and an 80% risk of mortality from the procedure. Her physician argued as follows (Slide 5) :

“stem cell transplant is the only **potential curative** therapy, it is **not** an experimental procedure, and it is clearly indicated at this time”

This debate about what is standard of care, unproven, best for the patient, consideration of the principle “first, do no harm”, etc. rages on. And it extends to the hundreds of new technologies- drugs, devices and procedures- that have grown explosively in the past ten years.

In an effort to be true to an evidence-based approach, borrowing from the academic world, we have developed a grid that ranks the strength of

evidence on the y-axis and effectiveness on the x-axis. (Slide 6). Strength of evidence increases from simple case reports- the weakest, to randomized controlled trials. Effectiveness is somewhat more qualitative, but we use two measures: harm vs. benefit, and weak vs. strong outcome.

Coverage of a health service, such as a new technology, is then based on where the evidence falls. If a technology falls within the right upper quadrant, labeled 1, where there is at least one randomized controlled trial that shows a strong outcome and benefit, it is covered because it meets the standard of care. On the other hand, a technology that has only been evaluated by several small consecutive series, with a trend toward being beneficial, is considered unproven, or investigational, and therefore not covered.

Without question there are gray areas- such as zones 2 and 3. Sometimes the acceptance of a technology into medical practice- laparoscopic cholecystectomy for example, precedes the published evidence. This example would likely fall into zone 3 and be covered. It is not always so easy.

Where medical evidence meets the world of health insurance, it is all about coverage- that is, what is paid for. Whether for each one of you as holder of an insurance policy, or for medicare and medicaid recipients, the practical question is “what is covered?” This is very real and very serious.

Which brings me to the contribution of scientific investigators to this process. In closing, I will cite several areas that need attention.

1. Definitions. It should not be beyond the realm of possibility that we as a society agree on the meaning of words like medical necessity and investigational. Today, this decision devolves to the insurance carrier, who then faces confrontation with practicing physicians, all of whom have their own definitions; the patient, who expects everything to be covered; and ultimately the legal system, advocating for its clients.
2. Choice of words. It is not uncommon for physicians, as patient advocates, to argue that a condition is rare, so it cannot be subjected to proper clinical trials. For example, I have heard the argument that any proposed cancer treatment for children is standard of care and since cancer is so rare in children a proper controlled trial cannot be done. That is to say,

investigational treatment becomes standard of care. And, of course, the definition of “child” tends to be a sliding scale to fit the patient in question.

Relative to published studies, it is not uncommon for investigators, who may believe strongly in the value of a new technology, to overreach in their interpretation of the data. Here is an example (slide 7) of a review of CT/PET fusion scanning for recurrent colon cancer. Based on one study of 21 patients and a second study of 65 patients, the reviewers conclude:

“ Overall, we believe that PET/CT fusion imaging should be the preferred imaging modality in these patients, because it identifies and localizes the disease in one setting and can guide diagnostic and therapeutic interventions”.

Treating physicians- and certainly plaintiff’s attorneys- frequently cite such comments from publications as authoritative. Objectivity, as difficult as it may be, must be an overriding goal.

3. Hope. It is not my intent to dash water on this basic human need. First, let me review briefly the issue of false hope. In the previously cited case of the woman with high risk MDS, her physician informed her that “the only potential curative therapy remains an allogeneic stem cell transplant”. He went on to quote her a “15-20% risk of treatment related mortality”.in contrast to the 80% mortality cited by PDQ. In a communication to me he stated “in fact, (stem cell transpant) is quite proven to result in long term disease free survival.”

It is not unusual for academic experts to argue for coverage based on the contention that when there is nothing left to try, trying a procedure that is “unproven” becomes the “standard of care”, and for us to deny coverage is therefore unconscionable. I contend that the brunt of these accusations should not be borne by insurance companies- the issue is much broader.

4. Evidence. It is widely accepted that the practice of medicine must be evidence-based. Within that framework I appeal to you in three areas. The first is clarity. Though I applaud efforts to quantify the strength of evidence, simply cataloguing it will not be enough. Here is a statement

from the PDQ, which is arguably the best evidence-based source for cancer treatment guidelines. (slide 8):

“An anti-CD 20 monoclonal antibody, rituximab, results in a 40%-50% response rate in patients who relapse with indolent B-cell lymphomas.” (level of evidence: 3iiiDiii)”.

This could be construed to suggest that rituximab is considered standard of care in this circumstance. But according to the level of evidence (3iiiDiii), this conclusion would be based on a non-consecutive case series (3iii) and an indirect surrogate outcome of tumor response rate (Diii). Does the evidence support the statement?

The quantitation of the evidence is clear. What to do with the information is less so.

A second issue around levels of evidence is accuracy. Again, since I refer to it so often, I will cite an example from the PDQ. (slide 9)For adult patients with recurrent acute myeloid leukemia, the author states:

“Low-dose palliative radiation may be considered in patients with symptomatic recurrence either within or outside the CNS.”

No level of evidence was assigned. The only citation is a single series from 1990, of which 8 of the 18 patients had AML, and there was 1 response.

Though this example is relatively minor considering the limited downside and the uncommon circumstance, the point has to do with the accuracy and precision of the message.

It is often challenging to know how much evidence is enough. Does one randomized controlled trial win the day? When do many small case series' add up to an argument for “standard of care”. The previous example shows how one small series can be wrongly extrapolated to represent the basis for a clinical practice guideline.

Finally, how do we get the medical profession to accept the power of evidence. It is a daily disappointment to me to see how often physicians ignore such resources as the PDQ, which I find to be the most authoritative guidelines available in the area of cancer treatment.

I hope these issues do not seem to you to be trivial. Sometimes I wonder when I read a disclaimer at the bottom of each cancer treatment guideline of the PDQ (slide 10) that says:

“The designations in PDQ that treatments are “standard” or “under clinical evaluation” are not to be used as a basis for reimbursement determinations”.

How else should we decide what is covered, if not by using an evidence-based tool like PDQ?

When all is said and done, what is covered by health insurance dictates our ability to afford comprehensive health care. Moreover, by defining the limit of coverage as that which meets “standard of care”, we have a powerful tool to rein in inappropriate, potentially harmful services, and to foster the research that provides us knowledge that is based on evidence. Your role in this ongoing effort should not be underestimated.. Thank you.