

***Overview of Draft Coverage and Reimbursement Report***  
**Cynthia Berry, J.D.**

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At the March meeting, the committee decided that this topic, coverage and reimbursement, would be the subject of its first major report. A draft report was prepared by staff, and can be found at Tab 5 of your briefing book.

I'd like to take this opportunity to thank Cindy Berry for her leadership on this issue, and Suzanne Goodwin, and Amanda Sarata for preparing the draft report. I think they have done a remarkable job in a very short amount of time. I think we should acknowledge, however, that this is a draft, and neither Cindy nor the staff have given it any "final blessing."

Also, as I indicated before, I doubt that we will complete the discussion of this topic here, but that it will proceed into the next meeting. So now at this time, Cindy is going to give us an overview of the scope and content of the issues covered.

Cindy?

MS. BERRY: Thank you, Ed.

In the interest of time, I'm not going to go into enormous detail on each of the topics that are covered under the report, but rather give a general overview of how the report is structured.

Many of you, Reed in particular, have looked at this in great detail and have provided some comments, and this afternoon's efforts are going to be focused on really taking a good, hard look at the report. So at this time, I'm not going to go over specific language. We all are going to have edits, comprehensive edits, I suspect, on some things that have been overlooked that we will want to make sure are included in the report, and there are things that may not be addressed adequately, and we'll need to flesh them out in greater detail. But I'll just give you a general feeling for how this report is structured, and then we can proceed to the discussion phase where we can get into some of the details.

As you may remember from the last meeting, we did have a pretty elaborate priority-setting process. Out of that process came coverage and reimbursement as one of the priority issues that this committee should look into, and coverage and reimbursement being one of the key barriers to access the genetic technologies.

The purpose and goals of the report really are to give an overview of the current state of play. What is going on right now in the area of coverage and reimbursement for genetic technologies and services, and how can we improve that?

The sections of the report are as follows. We have an introductory section of course. Genetic technologies and services, what are we talking about when we talk about genetic technologies? Reed has brought this up in the past, and I think we may need to do a little bit more work there as in particular, let's define this. What is the scope of genetic technologies and services that we're talking about? General principles.

Then in the background section, the report delves into our health care financing system in the United States. How are coverage decisions made in federal health care programs, and in the

private sector? How are services and technologies being reimbursed? What is the billing process? And then after that general overview, the report delves into the barriers to coverage and reimbursement, and of course the recommendations section is something for this committee to come up with.

Basically the introduction sets out what the problem is that genetic technologies can help enhance clinical care and improve outcomes, but there are limitations in terms of what is covered, and what is reimbursed, and those are barriers.

This section on genetic technology, as I mentioned, goes into what are we talking about when we talk about genetic technologies and services? What distinguishes them from other health care services and technologies?

The general principle section really has sort of an outline of some things that we have discussed in this committee in the past, and that undoubtedly we will delve into in greater detail in the future. It is not a comprehensive or extensive list, you will see others there at the bottom as we go through the discussion this afternoon, I think folks will come up with additional principles that probably need to be incorporated in this report.

As I mentioned, this is the general overview of our U.S. Health Care System, the different federal programs, the private sector programs, managed care, and then the issue of the uninsured, and underinsured. The section on coverage decisions reviews how Medicare makes coverage determinations, and then it goes into the private sector determinations, which really are varied. Every health plan is different, every health plan has different guidelines, and the results and outcomes are different.

The situation is really the same in terms of payment. In Medicare, you do have a system for determining what is reimbursed, and the report does go into what the current payment rates for genetic technologies and services are, and we'll undoubtedly have a discussion about whether those are sufficient. I suspect based on previous testimony and comments that we've heard, that payment is not sufficient for many of these services.

The report also goes into billing processes. Coding, CPT codes, and who is entitled to bill for genetic services and technologies. The next step, of course, is to then examine the specific barriers, barriers that are particular to the Medicare program, barriers to access that are particular to Medicaid and state programs, and then of course there are barriers that are applicable to all insurers, whether they are in the public or private sector.

We'll just run through a few of these very quickly. In Medicare, for example, the screening exclusion is one of the barriers that the report identifies. If there are no signs, symptoms, complaints, or personal history of a disease, and there is not an injury, it is going to be difficult, if not impossible, for Medicare to pay for a screening test. That, of course, is based on the Medicare law itself. It is not something that you can necessarily fault CMS for. They are going by what the statute dictates, and so this is a matter that we'll discuss later, is a change in the statute warranted.

The report goes into detail about local medical review policies and national coverage decisions. There is sort of a tension in some respects between local decisions as to what is covered, and then a national coverage decision. How do those interact, and how do they affect genetic services and genetic technologies?

Genetic counselors, are they able to submit bills to Medicare for their services? The answer is no, according to the statute. There are issues with regard to private health plans undoubtedly as well. Medicare is a national leader in health care. This is an interesting point, because in many, many cases, we see that Medicare really sets the stage and serves as a guide for other insurers.

So if Medicare covers something or doesn't cover something, often that is replicated in the private sector, but not always. My personal experience, and others will have experience here as well, when it comes to preventive services, oftentimes we see the private sector taking a more proactive role simply because the Medicare program is really bound by statute. As we all know, Congress doesn't move too quickly, and it is very difficult for a legislative body to keep up with advances in health care.

In this case, sometimes the private sector actually is able to move more quickly. So this will be a discussion in the report that explains why the Medicare program is so important, not only for the Medicare beneficiaries, but as a model for other insurers, but conversely, maybe there are some lessons that we can learn from the private sector in terms of their ability to incorporate some of these technologies in health care.

The report goes, as I mentioned, into state programs, and then we have barriers that are applicable to all insurers, and all health care programs. Medical necessity criterion, and of course one of the underlying issues, threshold issues that we will undoubtedly discuss in comments today has to do with the informational value of genetic tests, and genetic test results.

If it is just great for someone to know the result of the test, does that warrant coverage under a federal health plan, or private health plan. There is the issue of the future benefit, testing someone for a genetic disorder. If there is no treatment available right now, is that, again, an informational benefit? And also, if someone is not experiencing any signs or symptoms, if you test now, that will produce some benefit at some point in the future, is that a barrier to coverage, whether it is in the federal health programs, Medicare, or whether it is in the private sector?

Of course, the role of cost and coverage decisions. It is not explicitly considered in the coverage decisionmaking process, but undoubtedly it is a factor, and we'll have to be mindful of that.

Experimental exclusions. Some of these technologies fall under that category, and that's another barrier to coverage and reimbursement. CPT code modifiers, that's an important part of the report, because it outlines really the process for getting a CPT code, and what that means for coverage and reimbursement, and for payment. There are no CPT codes specific to genetic counseling, and that could be a barrier as well.

Evidence-based coverage decisions, we talked a little bit about that this morning. It is a current theme in our comments today, as well as what is going on in the report. Obviously a lot of insurers, rightly so, feel the need to have some kind of data with which to make a decision, and on which to make a decision to whether a treatment, test, or some technology or service should be covered.

We have talked a little bit about how important it is to have this kind of research available so that we can help make the case if certain technologies should be covered. Right now, there is a little bit of, and I think actually not a little bit, a pretty significant need for that kind of information.

The report goes into payment rates, and the issue of low reimbursement. It is not necessarily unique to genetic technologies and services. It is a common complaint, I think, from many

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providers of health care services. But the question is if the reimbursement is so low, and oftentimes is below the cost of delivering the service, or delivering the product or the test, what impact does that have on access?

There are broader issues that the report discusses. It doesn't attempt to resolve all of them, because these issues transcend genetics. They really go throughout the health care system, but we have talked a lot today about, and we will continue to discuss the issue of health disparities.

Education and training, we have spent a lot of time on that today. I think probably I should close with this, topics for discussion this afternoon. The overall structure of the report, the content, the tone of the report, the general principles, and then we have to come up with some recommendations.

Now, I'll bring up a point. In one section of the report if you have read it, there are some boxes on policy options. My view, it might be a little bit confusing to have policy options there, and then have recommendations someplace else. We might want to figure out how we want to structure that. I don't know if others agree or disagree, but I think the charge for this committee is to finalize the report, make sure that we've captured all of the basics, and that the language is something that we all feel comfortable with, but really hone in on some of the recommendations, concrete recommendations, that this report can make to improve coverage and reimbursement for genetic technologies, thereby improving access to these services.

Here are some of the topics, and I'll leave this slide up for our discussion. These are topics that staff have identified that we could go into all of them, some of them, a few of them, and it would be important to get the thoughts from the folks on the committee as to priorities, issues that you want to focus on, and that you think should be the basis for our discussion today for purposes of putting together some concrete recommendations for the last part of the report.

DR. McCABE: Thank you, Cindy.