Medicare Coverage Policies and Decision-Making
Sean Tunis, M.D., M.Sc.

DR. McCABE: Our next two speakers will give us an overview of Medicare's coverage and payment policies and decisionmaking processes for genetic technologies and services.

Dr. Sean Tunis, who is Chief Medical Officer, Director of the Office of Clinical Standards and Quality of CMS, will review coverage policies and decisions, and then he will be followed by Dr. Donald Thompson, who is Director of Ambulatory Services at CMS, who will cover payment policies and decisions.

Dr. Tunis?

DR. TUNIS: Well, thanks very much. I notice that we're running about 15 minutes behind, so I'm going to try to focus on just some of the major elements. And I also notice from the last couple of presentations that really all the whining is about payment policy, and that's why I brought a designated whipping boy --

(Laughter.)

DR. TUNIS: -- Don Thompson. The coverage stuff is really non-controversial, and I'll just whip through it, if that's okay.

Just as a broad overview, basically in order to get reimbursed for anything under Medicare, you have to deal with these five bullets, which are regulatory approval, a benefit category determination, coverage, coding, and payment. I'm going to talk about the first three, and then Don will talk about the last two.

By the way, I get to present so often with David Feigal of the FDA that he could probably give the rest of my talk, and you're welcome to it if you'd like it. We seem to find ourselves on the same panel about once a week, and I think maybe we'll switch jobs just for fun at some point.

Regulatory approval. Basically, you all have heard some of this before, but it's required for Medicare coverage if the technology falls under FDA regulatory purview. Regulatory approval is required for at least one indication, but Medicare has complete flexibility to cover off-label indications for uses of tests, devices, drugs, or anything else, and there's a lot of Medicare payment for things for off-label uses.

Obviously, any new guidance adopted by the FDA related to genetic testing, changing the regulatory framework, would affect CMS coverage by virtue of the fact that we would follow that regulatory oversight. On the issue of home-brew tests, since they may not be under the FDA regulatory purview, they do not require FDA approval in order to be reimbursed by Medicare.

So really not much more needs to be said about the regulatory issues.

The next issue in some ways becomes one of the key issues regarding some of the limitations around Medicare reimbursement for genetic tests, and that's the benefit category issues. Medicare is a defined benefits program, which means we can only pay for things that are specified benefits within the Medicare statute, Title 18 of the Social Security Act. So as examples of defined benefits, there's inpatient services as a benefit category, outpatient services, ambulance services,

durable medical equipment. As some of you might have noticed, a new benefit category was added in December of 2003, prescription drugs. So those now become payable by the Medicare program, couldn't be paid for before because there was no statutory basis to do that.

Diagnostic services are a benefit category, whereas screening services and preventive services are not. So obviously, the critical issue is what's a diagnostic service and what's a screening service, which turns out to be a rather subtle distinction and an important distinction.

So, first of all, this is kind of current policy in Medicare. You have to ask around a lot to actually get this laid out for you. But for purposes of diagnosis, the distinction here is based on whether a person has signs or symptoms of disease or a personal history of illness. So obviously, someone with a history of multiple colonic polyps, they have a history of disease. Genetic screening in that case may be considered coverable.

A strong family history would not by itself qualify to make a test a diagnostic test. So genetic testing in high-risk patients with a family history of breast or ovarian cancer would be considered screening, no matter how high the pre-test probability is. It's still considered screening. In some sense, the proof that this is the way the program is set up is that last year we had a discussion about diabetes screening for high-risk patients, and there was a lot of discussion at the Department of Health and Human Services about whether we had the legal authority to do diabetes screening in patients with no signs or symptoms of disease simply based on a profile that would make them very high risk for having diabetes.

Essentially, the outcome of that suggests to you what the answer is, which is diabetes screening was just added in the Medicare Modernization Act as a benefit under Medicare. Now, that having been said, our general counsel has long held the view that there is nothing in the statute that actually explicitly prohibits us from designating testing in high-risk individuals with no signs or symptoms of disease and no personal history, nothing that stops us from deciding that that is diagnostic testing. But in order to do that, we would have to go through rulemaking because it's been longstanding agency policy that that's not how we approach it.

So if you all were interested in tomorrow deciding what kind of interesting windmills you'd like to approach, one of them would be rulemaking around genetic testing, not that I'm suggesting it.

Obviously, any tests that identify a treatment responsive subpopulation, most pharmacogenomic tests, would be diagnostic tests because those are done in patients who have existing signs and symptoms of disease, generally.

So that is, kind of in a nutshell, the benefit category issues. Obviously, because of the current situation regarding screening versus diagnostic tests, many of the genetic tests that you all are concerned about are not an issue from the perspective of Medicare reimbursement. We can't reimburse them under the current scenario.

Under the situation where tests would fit within the benefit structure and would be potentially coverable, then you move on to the coverage issue, which emerges from Section 1862(a)(1)(A) of the Social Security Act, which says that coverage and payment are limited to items and services found reasonable and necessary for treatment of illness or injury. You've heard a lot of discussion earlier about medical necessity, reasonable and necessary, how that's defined, et cetera.

The Medicare program makes coverage decisions at the local and national level. By local level,

we mean the Medicare contractors around the country who process claims for Medicare, the local insurance companies. In the absence of a national policy, the policies of those local insurers who process Medicare claims are the coverage policies. Those are called local coverage decisions.

We haven't talked about it a lot today, but cost, cost-effectiveness, cost-benefit analysis are not considered formally in making reasonable and necessary determinations within the Medicare program, and the asterisk there is just there to say that's a longer discussion. I wouldn't want to stand up here and suggest that economic issues are not a factor, and I'd be happy to answer questions on that if I'm still around during the panel discussion.

So in terms of current situation around coverage policies for genetic testing, we have one national coverage decision, which is on cytogenetic testing, and it specifies it's covered for AML, acute leukemias, congenital abnormalities, and myelodysplasia, I believe. That policy actually dates back to 1979, was updated in 1998, I believe, through the national coverage process.

So most other coverage basically, to the extent that there is a test paid for, is under local coverage decisions. A number of the contractors do pay for HER-2 testing. There are some that pay for BRCA testing, although most don't because they consider it to be screening and they are under the same obligatory purview in terms of screening versus diagnostic tests that applies at the national level.

So we ran some numbers for 2002. Don's folks did this earlier today. There were 270,000 claims paid at a total cost of about $13 million. Well, we almost never do a national coverage decision on anything that is less spending than $50 to $100 million. That's not a firm or fast cutoff. That just tends to be the way it is, that we're not going to deal with issues that have less impact. So it's likely that there's going to be more national coverage decisions with coming advances in genetic testing, pharmacogenomics and personalized medicine. So the national coverage process may not be particularly relevant to you all now, but it probably will become more relevant as this field advances, particularly if you can get that little thing fixed related to family history of disease and high-risk patients.

There is a formal process for developing the coverage decisions by the contractors, the medical directors, carrier advisory committees. There's a development of draft policies, et cetera. So they do have a formal process. There's even a process for reconsidering policies. They basically also apply reasonable and necessary, and I'm going to give you the current definition of reasonable and necessary in a moment. I'd just like to point out that at the local level it's understood that more weight is placed on expert opinion versus empirical evidence. So it tends to be more of a consensus-weighted process as opposed to an evidence-weighted process.

So in the context of an earlier stage of development of the evidence around genetic testing, my guess is that there's going to be a lot more tests added at the local level before we ever get any additional tests actually covered at the national level. Local policies are not binding on administrative law judges, and they can be appealed. When there's variations amongst different local coverage decisions in different jurisdictions around the country, that will often be a basis for something being referred up to the national program for a national coverage decision.

This is the diagram of the national coverage process. Again, we could spend a long time on this, but basically this is just to emphasize that there is a formal articulated process. This is in the Federal Register written out just this way. It involves the possibility of technology assessments being done, usually through the Agency for Healthcare Research and Quality. We have a Medicare Coverage Advisory Committee, and the time frame for this is now six to nine months.

These are new time frames that were imposed as a result of the Medicare Modernization Act. We had target time frames in the past which we applied rather loosely. So anyway, now there's a nine-month time frame during which a decision had to be made.

So here's the definition from Medicare's point of view of what's reasonable and necessary. There needs to be adequate evidence to conclude that the item or service improves net health outcomes, and in terms of health outcomes we emphasize outcomes that are actually experienced by patients. So functional status, quality of life, psychological outcomes, as well as morbidity and mortality, all of those are meaningful outcomes when it comes to evaluating the impact of a diagnostic test.

We usually look for evidence that's generalizable to the Medicare population because there are sometimes significant differences between the performance of the technology, including genetic technologies I imagine between younger and older populations, and we also look for things that are as good or better than currently covered alternatives. We use a standard evidence-based framework, the same sources of evidence as I think Michele Schoonmaker put up, published literature, systematic reviews, expert guidelines, et cetera.

The key factor here is that we weight the evidence based on the source and the methodology. The whole evidence-based medicine approach basically says you put more emphasis and place more weight on evidence from sources that have less potential for bias.

So let me just talk, then, about determining the adequacy of evidence related to diagnostic technologies. We use a framework which is not unfamiliar to anyone here, but it was articulated by our Medicare Coverage Advisory Committee, that basically there are sort of two critical pieces. There is test performance, the sensitivity and specificity or accuracy of the test, and then there is the clinical utility, impact on patient management and outcomes. In some cases, of course, the clinical utility will depend on there being a beneficial intervention available.

So then we come down to an important question, which is under what circumstances does information itself provide benefit? Well, we certainly don't assume that information itself and increased certainty is inherently beneficial. At least, I'm not aware that that's an assumption that we've been using.

So the value and the impact of the information is likely to vary by the test and by the specific clinical circumstances, and what I would say is that ideally, if one is going to argue for the benefit of information, whether it's a Huntington's disease test that presumably affects people's lifestyle choices or other factors, we would look for some evidence to empirically demonstrate that the information in fact has that impact. Simple qualitative arguments that that might be the benefit of a test are not going to be sufficient, at least at the national level, to merit coverage.

So that covering the regulatory issues, the benefit category issues, and a quick intro on reasonable and necessary, and we'll let Don take all the hard stuff.

DR. McCABE: Thank you.