A Clinicians' Perspective on Reimbursement of Genetic Technologies and Services
Marc Williams, M.D.

DR. McCABE: Our next speaker will be Dr. Mark Williams for a clinician's perspective. Dr. Williams is a pediatrician and medical geneticist at the Gundersen Lutheran Medical Center in LaCrosse, Wisconsin.

Dr. Williams?

DR. WILLIAMS: I thank you for the opportunity to be able to speak to the committee. I don't know if speaking or whining is perhaps the operative word here. I'm having flashbacks of dealing with my teenage daughters, I'm afraid.

But let me give you a little bit of perspective of a clinician. I'm going to be talking about four different areas, billed services, touch a little bit on multidisciplinary evaluation, access to services, and some issues relating to problems as I see it with the current system.

If we look at actual procedures, they really fall into what we truly think of as procedures, which is amniocentesis, CVS, or infusion, and for the clinician what are called evaluation management services or E&M, and I'm going to talk about each of these separately.

Procedures themselves are pretty straightforward. The indications are straightforward. You do an amniocentesis for advanced maternal age or for a known chromosomal abnormality, and there are specific CPT codes that cover those particular procedures. Now, that being said, there are of course some insurers that may choose not to cover certain indications, as Dr. Schoonmaker said earlier, and it has to do with exclusion of genetic tests or lack of a benefit.

I wanted to spend a little bit of extra time on infusion because there's something new on the horizon here that's going to really impact this not so much for genetics, although that's going to have some impact on us, but particularly hematology, oncology, and some of our colleagues here, and that's the Drug Improvement and Modernization Act of 2004. This defines reimbursement for the infused drugs and biologicals. Essentially, what has been determined is that existing drugs will be reimbursed at 85 percent of the average wholesale price as of April 1st of 2003. New drugs will be reimbursed at 95 percent of their average wholesale price.

Well, this has significant implications for treatment of certain genetic disorders where enzyme therapy is now becoming available, specifically Gaucher disease, Hurler-Schie, and Fabry syndrome. Because these are orphan diseases, the enzyme replacement is very expensive depending on the age and size of the individual, anywhere from $100,000 to $250,000 a year. It's not an uncommon cost. If the reimbursement is not going to be covering the cost of the medication, that could present access issues for the patients that need these novel therapies.

Now, when we talk about evaluation and management, there really are several things that need to be addressed and which I will go through briefly. First is the RV/RVU disparity, and that is that E&M reimbursement is reimbursed at .04 RVUs per minute, whereas procedures are reimbursed at .08 RVUs per minute. So for those of us that don't use scalpels or needles very often, our time is being reimbursed about half of that of our colleagues who do procedures.

This is then combined with the issue of how the E&M is actually scored, and I'm going to tell you the system under which we're currently operating and then give you a brief look into a brave new

world. The history, it's possible to have a level 4, which is the highest level of a history intensity and not even do a family history. The system as developed really can be done without a family history, and you don't have any ability to bill more intensively for that.

Physical examination, again, is based on a number of elements. The elements of the dysmorphology examination, which is very specific, are generally not recognized as elements, although I think it's also fair to say that there are three different element systems out there dating from 1995, 1998, and 2000, all of which are different and all of which can be used to provide documentation to third parties, although depending on the third party, which one they choose to use can vary. And then the third aspect of E&M is the so-called complexity, which is meant to adjust for the seriousness of the condition, risk of mortality, the complexity, but the elements in this part are very poorly defined and are very subject to interpretation.

Now, I want to spend a little additional time on family history because that's sort of the geneticist's bread and butter, as you might expect. The standard that we hold ourselves to is a full three-generation pedigree. We frequently are using statistical analysis, including things like Bayes theorem and some of the cancer risk models that are available. We submitted -- "we" meaning the American College of Medical Genetics -- a CPT code, actually two CPT codes for pedigree analysis to define this as something different from family history and use that as a separately billable code to allow us to be able to capture some reimbursement for the complexity of this pedigree analysis that we do.

We had an interesting thing happen, which was that just before the vote to approve these was going to be taken by the CPT panel, they said, well, we've got this new E&M system; we need to vote on that and then we'll come back to the pedigree analysis. They approved E&M, which I'll go into in just a bit, and then they said, well, now pedigree analysis falls into the new E&M, so it's off the board. So that was an interesting little end-around there.

Well, the new E&M is going to completely get away from the element system that we've grown to know and love. It's going to look at time components, with a maximum time or a level 5 component of approximately 60 minutes. The issue with the new E&M is that the members of the AMA have basically said we don't want the elements, we don't want the documentation, so we're going to develop these clinical scenarios which are really going to define our levels of care. The perspective that I see and that I think Dr. Tunis is probably going to be struggling with in the not-too-distant future is how do you audit that? How do you make sure that people are really doing what they say they're doing? The only way I can really come up with is to audit by time.

Well, genetic encounters, as we've already heard, are not infrequently two to three hours face to face. So if we're limited to a 60-minute time, that's going to be problematic, and there's not direct multiplicity of the level 5 versus the level 1. So if I do eight level 1 codes, which I would do if I was wearing my pediatric hat and looking in ears, I can bill much more per hour than I can bill doing one one-hour evaluation.

The other thing that is not captured here is the pre- and post-encounter time, and this is something that really has never been built into the CPT system, although there are some modifiers that we do have access to that can take into account pre- and post-encounter time. But as we heard from the previous speaker, it is not unusual at all for third parties to reject these modifier codes, and again the reimbursement does not reflect actual time.

Now, there are also codes for coordination of care which we also spend a lot of time doing. Again, these are frequently rejected and do not usually reflect actual time.

The issue of physician profiling. This is an audit technique used by third-party payers. It is used to adjust claims to make sure the practitioners are playing by the rules. It's used to adjust charges, and while we're usually told that they can be adjusted up and down, the reality is that they're usually adjusted down. The geneticists have a real problem because we frequently are listed in provider networks -- since we're not able to do a genetics residency, if you will, we do a prior training, usually in pediatrics or internal medicine or Ob/Gyn. We then do our fellowship in medical genetics. We get listed in the network as a pediatrician or an internist, and then we're compared or profiled against pediatricians and internists, and as you might suspect, the code profiles are significantly different.

I get information from my pediatric department, and I can tell you that about 95 percent of the codes that I submit are level 5 codes, whereas my colleagues, generally 1 to 2 percent of what they do are level 5 codes. So when a third-party payer sees that, that can lead to problems saying, well, you're really not doing that, you're just trying to get more money out of us, and can lead to fraud and abuse investigations, or just automatic down-coding.

I mentioned the new and improved E&M that will eliminate the elements. These clinical scenarios are going to be developed by specialty societies to define their CPT levels. My current understanding of the process is that there is sort of a beta test of societies that are developing their clinical scenarios to be brought back to the CPT advisory group, and once that analysis is complete, then all societies will be given those as guidelines to go out and do that. Implementation is supposed to be January 1, 2005. Quite honestly, I don't see how that's possible, but that's what they're shooting for. As I already alluded to, the issue of auditing this is going to be, I think, a real nightmare.

Multiple providers. We talked about multidisciplinary clinics. Dr. Bachman indicated that it is expensive to provide care that way, although I would argue that if you have an individual that has something like a cleft palate or spina bifida, you're really not going to save any money by having them see the individual practitioners separately. They're still going to have to see everybody. It's a matter of bringing them all under one roof, and so it's an issue of patient convenience. However, there are prohibitions about multiple providers billing on the same ICD code on the same day. The first one in, only one paid is the rule of thumb, so it does encourage some efficiency in terms of getting your bill turned in.

Now, in the Down's syndrome clinic where I work at, where we have myself and the developmental pediatrician and speech therapist and others, we have a variety of diagnoses I can use. I use the Down's syndrome code, the developmental pediatrician uses the mental retardation code, so we have different ICD codes that we can use. But if you're in the cleft palate clinic, you're basically stuck with that cleft palate code, and that's going to limit the ability to reimburse because of that ICD restriction. This impairs coordination of care, it inconveniences patients, and it decreases, in my opinion, the quality of care.

The last issue relating to multiple providers is the role of genetic counselors and the issue of billable entity status for genetic counselors. The bottom line is that genetic counselors are not recognized as a billable entity, with the exceptions of Washington, Texas, and Ohio, which is pre-HIPAA, which we'll get to in just a bit. Genetic counselors have traditionally not been licensed, although in Utah and California licensure for genetic counseling has been passed. There are restrictions relating to "incident to" billing which are relevant.

"Incident to" basically are services provided by a health care professional under the supervision

of a physician, which are billed under the supervising physician's UPIN. While I don't want you to get overly concerned about this slide, the first part of it is relevant. This is directly from CMS rules and regulations. "If an employee of the physician provides genetic counseling and that person is not a nurse practitioner, physician's assistant, certified nurse specialist, or certified nurse midwife," -- all four of these having a specific payment recognition in Medicare -- "then genetic counseling can only be billed by the physician as an E&M CPT code 99211."

A 99211 is basically office with an established patient, minimal problems, five minutes spent performing. This 99211 was developed for nurses who were providing, for example, immunizations, where they were giving counseling to the parents about the side effects of immunizations. That's what this code is for. But because genetic counselors are not specifically recognized within Medicare with a payment category, they are not able to bill "incident to" at a higher level, as are these folks who can basically have access to all of the E&M CPT codes.

Now, there are a few ways that we can sometimes get around it. Hospital-employed counselors can be billed for as part of a facility fee that's not available to non-hospital-based practitioners. Washington State has mandated coverage of genetic counseling and issues billing ID numbers to certified genetic counselors. They are the only state at present that is doing that. I mentioned before Texas and Ohio. Texas and Ohio had also developed private codes, local codes to allow for reimbursement of genetic counselors. However, one of the side effects of HIPAA was that all local codes disappeared. So all of those systems that were developed have been lost to use in those states, and to my knowledge have not been recovered.

Even though counselors have licensure status in California and Utah, my understanding is that billing rules are still pending, and so whether they'll actually be granted billable entity status in those states is up in the air.

What does this affect? Well, it affects access. Systems don't offer genetic counseling if there's no reimbursement for it. We heard about the labs getting reimbursed at a percentage of cost. Well, the percentage over zero is infinity, so that is a bit of an impediment. Productivity-based reimbursement limits geneticists in the private sector. In other words, if you're in a standard medical group where your reimbursement is specifically related to how much work you do, the amount of work that you're actually able to bill for, given the limitations of the E&M system, really does not make it financially viable in the traditional medical group, although in groups like the group I practice in in Kaiser, where we're on a salary basis, groups can make the decision that this is a value added, and then they'll try and make it up somewhere else.

Geneticists are consequently not seen in health plan networks, in the PPO networks that Michele referred to, and there may be referral requirements to see a geneticist or the traditional gatekeeper model. We're seeing a little bit less of that, but I think there's still the perception that genetic services are expensive and are for only the very few, therefore they're really not necessary.

Now, I think there are a little bit of things to be hopeful about. The first is that in 2006 we'll all be issued new numbers, thank heavens, national provider ID numbers, NPIs. Our understanding from the interpretation of those rules is that anybody that provides medical services will be eligible to have an NPI. That means that genetic counselors will be eligible to have an NPI. The major problem that genetic counselors have right now is that even if a third-party payer wants to pay a genetic counselor -- for instance, Aetna mandates genetic counseling prior to certain of their cancer predisposition tests -- the genetic counselors can't get into the computer because they're not a billable entity. They can't get a UPIN, they can't bill.

If they have an NPI, then certain third-party payers may be able to allow genetic counselors to use that NPI and be allowed billable entity status. There may be some state initiatives that are going to come along. The HCPAC, which is a representative of non-physician allied professionals that sits at the CPT advisory council is developing CPT E&A codes. This is evaluation and assessment codes for genetic counseling to be brought to the CPT Advisory Group and Editorial Panel, and if these are accepted, once a CPT code is in there, basically anybody can use it. So that may help some.

Then, as we're going to hear about a little bit later, research on the impact of genetic services on cost and quality of care are out there. There's going to be more of them, and I think we're going to be able to make a better case for why there is a need for our services.

Thank you very much.