

Cluster 1: Coverage and Reimbursement for Genetic Services
Marc Williams, M.D.

DR. WISE: Cluster No. 1.

DR. WILLIAMS: A wise man once said that when anybody says it is not about the money, it is about the money. I think anybody that has listened to any of the discussions that we have had at this Committee, both at this meeting and any other meetings, know that issues of coverage and reimbursement come up frequently.

I first got involved with the old SACGT on reimbursement issues back in 2000, working with Suzanne Goodwin, and have been working on and off with this through a workgroup on the report that is listed there under the first sub-bullet. In some ways, a lot of what we are going to be reporting here are things that are already in progress and that we just need to continue to do.

Essentially, as we have heard, there have been some unresolved issues from the February 2006 SACGHS report. We are basically continuing to pursue those unresolved issues. We are looking at strategies to hopefully remove some of the obstacles to implementation of some of the recommendations that we put forward.

But we have also been looking at identifying new issues. This, again, ranges from things relating to Medicare coding, billing, payment, and reimbursement policies.

The report that I referenced had nine recommendations, and there have been a number of things that have occurred since that report which we have heard about at previous meetings, so I am not going to walk you through these.

We also heard from Steve yesterday in regards to the last sub-bullet there that we have been told and are expecting a letter from the Secretary's representatives later this month regarding some of the follow-up issues that we had discussed at our last conference call and also in letters that have been going back and forth this year.

The policy questions that we are really interested in focusing on are approaches to revised payment rates to reflect the true cost of the genetic test. We know that the Medicare fee schedule at the present time has a lot of these tests relatively undervalued compared to their true cost. While there have been some efforts to look at invoking things such as inherent reasonableness to address some of these fee schedule issues, we have not been particularly successful in terms of being able to make any movement there.

This is an issue relating to offering tests and to some degree, as we talked about yesterday, also impacts access to testing.

The billing related to certified genetic counselors has been an ongoing issue, in particular how we can get access to CPT E&M codes to enhance access to genetic counseling services, which we think will be increasingly important based on the increasing visibility of genetics in clinical practice and the importance of this in terms of informed decision-making prior to embarking on testing.

As we saw some of the costs of the tests yesterday, I think all of us that are at least even mildly affiliated on the payer side would really like to make sure that the people that are going forward

with testing are good candidates for testing and actually that is what they want to do. So genetic counselors have an important role to play, at least in the traditional genetic testing field.

There have been new issues that have arisen since the 2006 report. One of them relates to the application of reimbursement audits, specifically medically unlikely edits, to procedure-specific CPT codes where, in the course of processing DNA, certain CPT codes are done in multiples, sometimes many multiples. There was a movement to apply medically unlikely edits so that those multiples would be kicked out and only one CPT code of a given type would be paid for. So we have been working to say this is probably not actually reflective of the work that is happening in the laboratory.

That at least is on hold at the present time, but we haven't had any resolution to that issue.

We have talked a lot in this Committee about family history. We heard yesterday from Steve about the roll-out of Version 2 of the Surgeon General's Tool. There has been a lot of effort from a number of agencies both within DHHS and also throughout other areas of the government that are providing health care about using this Family History Tool as the de facto standard for family history collection within government-provided health care.

But we still are left with the issue of how do we actually use the family history and then how do we fairly reimburse for that. In particular, the idea is using family history in the definition of a personal history of disease so that we can meet reasonable and necessary standards for Medicare coverage.

We have put forward several possible recommendations, or as Jim would say, a range of recommendations.

[Laughter.]

DR. WILLIAMS: I'm sorry. I should have had another sip of coffee before I started, perhaps.

But, is there a way that we could use some of the current evidence groups such as EGAPP or USPSTF to define cases in which family history of a disease could be considered to be personal history, which would allow coverage for some interventions.

We are also looking ahead to August 2009 and the NIH-sponsored State of the Science Conference on Family History, which will really probably give us the best assessment of where the current evidence is relating to the science of family history.

Again, how can we look at the current reimbursement system and say, if you are doing something beyond just asking "Do you have a family history of anything?", if you are actually doing analysis of pedigrees and this sort of thing, which is work that is outside the current family history within the evaluation and management codes, then is there a way to reimburse people for doing the extra effort there.

In conjunction with the Pharmacogenomics report that came out a year or so after the Reimbursement report, the idea is to raise pharmacogenomic testing as a national coverage decision issue that could be looked at by CMS and then how that would fit into the idea about whether pharmacogenomic testing would be considered to be a diagnostic test. In that case there could be consideration of coverage from CMS in situations where the evidence warrants, versus the concern that pharmacogenomic testing would be looked at as a predispositional test, which

SACGHS Meeting Transcript
December 2, 2008

right now is excluded from coverage under the Medicare statute. So this is an issue that really needs to be resolved.

Then, ultimately, how do reimbursement issues impact access to genetic services and how can we improve that in populations that are currently being underserved.

Possible action steps. We are going to continue to monitor the recommendations from the 2006 Coverage and Reimbursement Report. We have ongoing discussions with CMS officials relating to that laundry list of items there. Hopefully we will get some additional communication before the end of the year that will let us know what has been done and what needs to be done.

We are engaging with the laboratory community to again look at generating support for the application of this inherent reasonableness authority to the clinical laboratory fee schedule. That might provide some relief for some of the molecular codes, although what we were told in our phone call was that if we open inherent reasonableness, it is open for everything.

So the tradeoff could be, while we get some increase in molecular codes, there may be decreases. So, does the laboratory community as a whole look at this as a benefit to open this or would this be something where there would be more harm than benefit that could potentially accrue.

We want to look at the authorization act, the Patient Providers Act of 2008, looking at clinical preventive services and coverage through CMS, if USPSTF recommends that and if the MedCAC concurs, to see whether or not there are some aspects of what we are doing, particularly around family history, that could be folded into that.

We are trying to encourage collection of demographic data so that we can have a better sense of access to and utilization of genetic services in underserved populations.

So that is a very brief overview of what we are doing. Most of it is a continuation of things that this Committee has already signed off on. Hopefully, we will be able to pursue those things. I'm happy to answer any questions.

DR. WISE: Questions for clarification?

DR. FERREIRA-GONZALEZ: Do we discuss now if we need to add a point or later in the afternoon?

DR. WISE: If it is a quick addition or a quick point or a clarification question, it would be great to do it now. If it is a more complex suggestion or issue, then we should probably leave it for the full discussion.

DR. FERREIRA-GONZALEZ: There are a number of laboratory associations in the community and even in industry that are looking at review of the coding for genetic testing as a monitor. We might want to engage these professional organizations on an ongoing basis to maybe come back to us to report on some of the efforts. Maybe we can be informed so that all these different groups, who might not be talking to each other, can actually work in a single group.