

Date: 5/7/07

Event: Insurance Basics on Cochlear Implantation and Baha: Helping Parents Negotiate the System

DONNA SORKIN: Good afternoon. This is Donna Sorkin from Cochlear America and I want to welcome you to our HOPE on-line course on insurance basics this afternoon. We're excited to have with us the industry's foremost authority on this topic, Cochlear's own John McClanahan. John will be starting the presentation in about 5 minutes on the top of the hour. And I do want to remind you that we are offering captioning or CART at this session. So those of you that would like to have that option, there should be an e-mail that came to you a little bit earlier on how to do that. This also means that there will be a transcript of the day that everyone is free to also have. We're offering that form of access today and hoping to refine that and being able to offer it going forward.

So again, we're really pleased to have all of you with us today for this topic. Very important topic for you to be able to assist your families with. And we'll be back with you in just about three minutes. See you at the top of the hour.

DONNA SORKIN: Good afternoon, everyone. This is Donna Sorkin from Cochlear Americas' Hope Program. I want to welcome everyone to our session today on a very important topic, insurance basics. I also want to

remind you we are offering CART or real-time captioning during this session. And you should have received an e-mail telling you how to do that, how to use that option. And it also means you'll be able to receive a transcript of the session after today's event if you wish to do so.

So let's move to the opening slide, insurance basics on Cochlear implantation and Baha: Helping families negotiate the system. A very important topic for all of you working with families, regardless of the setting.

I want to just move on to Cochlear Americas's commitment to educational outreach. Most of our sessions have focused on educational or rehab topics. We felt that this very important topic also belonged under HOPE. It's an issue that many of you encounter. You're working with families, both on the surgical portion of the intervention and upgrades, as well as the rehab portion. So we'll be covering all of these topics today with our speaker.

Next slide, John McClanahan is senior director of reimbursement and funding for Cochlear America. He has been with our company for over 10 years and has really been national, perhaps international expert on this topic. John is responsible to the day-to-day aspects of Cochlear's reimbursement department, as well as all of our long-term efforts to expand coverage and payment. I've been very privileged to work with him during my tenure at Cochlear on various initiatives to expand coverage and payment in both the public and private realm. He has 40 years in the healthcare arena, including clinical, health insurance, and reimbursement.

I think he must have started when he was a mere baby. And he's been very kind to include his e-mail address there for you so that you can address any questions that you may have after the session with him.

With that, I'm going to turn this over to John McClanahan. You're in for a real treat. And I'll talk to you again at the end of the hour.

JOHN McCLAHANAN: Good afternoon, ladies and gentlemen. This is John. Donna, thank you very much for those kind words. Over the next hour or so, I want to talk to you a bit about health insurance basics for the products that Cochlear Americas supports, and that's the Baha integrated implant and the Cochlear implant. We'll spend a bit of time on the payer world just to orient you. We'll talk a bit about professional services. And by that I mean programming, rehabilitation, audiology services, speech language pathology services, and some ADVT to some extent. We'll talk about the current environment for patients and recipients to access external parts and accessories, because as the implanted base begins to grow, among all three of the principal manufacturers, the demand is the importance to have access to external parts and accessories: Batteries, repairs, cords, cables, those kinds of things becomes critical. Spend a few minutes on the recent developments and sort of the lay of the land for bilaterals and one or two slides on the importance of advocacy.

But first, the obligatory commercial, the reimbursement department at Cochlear Americas has been around since 1988. Now, keep in mind that Cochlear's first device was approved for marketing by the FDA in 1985. And Medicare approved coverage for Cochlear implants in 1986. So in

relatively short order, and this, of course, was way before my time. In relative short order, the company realized that reimbursement support and an active program in developing reimbursement tools, policy, and strategy was going to be critical to the success of the technology.

So right now, the company has six basic services that fall under reimbursement or work closely with the reimbursement program. The preauthorization service we call OMS, and it's been around for almost two decades. OMS stands for otologic management services, and it is preauthorization and verification insurance benefit research organization, and we provide these services at no charge. And that's something that we consider as part of doing business, to help not only our customers, but our recipients work or deal with the health insurance environment in the best way possible.

We have a consulting service and we provide information and assistance. And this is usually to clinics or providers who feel that they want to investigate a startup program, either for the Cochlear implant or the Baha device. We also consult with families and insurance companies to try to answer questions, clear confusion, do anything we can to help expand and proliferate the coverage for these two pieces of technology, as well as to the greatest extent possible the professional services associated with this technology.

We have a billing service. And that takes a couple of minutes to explain, because often, that is very confusing why we manufacture or have a billing service. Well, Cochlear is a Medicare provider and Medicaid provider for

half of the state agencies in the country. And by virtue of that providership, we can build parts and accessories and services specifically for the external components of both pieces of technology, both products directly to Medicare and the Medicaid agencies with whom we're contracted.

We also have some working arrangements with other state programs and, to a lesser degree, we work with commercial plans. And those are the Aetna and the United Healthcare and the Blue Cross/Blue Shield. We do not, at this point, have any -- we haven't signed any provider agreements or become part of anybody's network, and I doubt seriously if we will ever do that, but we have, in the past, and will, in the future, work with these companies to do everything we can to ensure that our external components, particularly sound processors, speech processors that access, can be had by the commercial -- by the recipients of the patients.

We have a warranty program, and this warranty program is focused on the internal components. And it's been with the reimbursement department since day one, but our objectives are twofold. One is we want to minimize the angst and the worry and the concern that failed devices carry, obviously, and we want to try to minimize any out-of-pocket costs that the family or the recipient incur. We have a vaccination support program, and for those that are interested in vaccinations, meningitis vaccinations, we will either find coverage and benefits within a patient's policy or, failing that, we will go ahead and fund a vaccination for that family.

And then I work with Donna. As she said at the top of the hour, on strategic initiatives. And over the last five or six years, we have managed

to expand coverage within Medicare's coverage guidelines. We've managed to improve the way Medicare pays for Cochlear implants at least every year except one where we've gotten between 7, 8, and 9% increases.

We also have managed to get Medicare to cover Baha and to provide some pretty favorable payment methodologies that are applicable to that technology. So Donna and I have worked very closely together, and I think we've made a difference and I'm very proud of that.

Let's spend a few minutes on the payer world now. I have about an hour's worth of conversation and there's no way that I can impart to you all the details and the nuances of health insurance, and I'm not sure that many of you are that interested in it. So I've tried to take a rather high approach to it just to give you frames of reference. And in some cases, detailed information that I hope will help you in your endeavors. And I think the first thing we need to do is talk about the payer world and why it is so complicated and sometimes difficult to deal with.

In the United States, we currently have about 300, over 300 million Americans who are in our population, at least according to the latest census. Of that total number, there are about 60% who are covered by commercial plans. And by that I mean Blue Cross and Blue Shield or Aetna or United Healthcare. There are six large insurance companies and probably well over five hundred smaller plans and companies that actually comprise the commercial health insurance industry in this country.

Of that 60% of Americans who are covered by commercial health plans, Blue Cross and Blue Shield has the lions share of the business. Blue Cross and Blue Shield is literally the big dog in the yard, and we make sure that when we're thinking of strategy and how to approach coverage for not only the devices, but the professional components, we also are very -- we're very cognizant of Blue Cross and Blue Shield's needs.

27% or, roughly, 82 million Americans have public plans. And that's federal, state, or local government programs. Federal is, of course, the biggest one recognized by literally everybody as Medicare. State programs, Medicaid. But there are also some children's health insurance programs that are also included in this number. But about 27% of all Americans are covered by some sort of public plan.

48 million or about 16% have no coverage, sadly, whatsoever. And depending upon the economy as it ebbs and flows, that number can get up to as many as 75 million Americans without coverage.

How about cost of healthcare or who spends the dollars required to pay for the healthcare we receive? I think this pie I've used for many years, and I think it's a good visual to get a sense of that. In 2006, there were two trillion dollars spent in healthcare in this country, and of that, 35 cents out of every dollar came from commercial plans. Again, Blue Cross and Blue Shield or Aetna. Medicare paid for 17 cents out of every dollar. Medicaid paid like amount, 16 cents out of every dollar. Other public payers like the Veterans administration or the Department of Defense paid an additional 12%. Alternative forms of funding or philanthropy accounts for

about 7%. And as healthcare consumers, you and I should be interested to know that 13 cents out of every dollar is paid for -- for healthcare is paid out of my pocket. My pocket? Out of our pockets. So 13% of 2 trillion dollars is quite a lofty sum.

So the take-home message from this slide is that insurance company payment is critical, not only to access, but in many cases to the continued viability of a provider or a clinic or an individual clinician. And you add these up quickly, 80%, over 80 cents out of every dollar paid by an insurance company. So it behooves us all to understand how the payer world works, at least to some level. There's a growing cadre of professionals out there who deal with reimbursement as a way of life as a profession. To this point, generally, these people have come from hospitals or billing services, but now it's rapidly being recognized as a discipline all its own.

Let's talk a bit more about insurance companies. Commercial plans cover, as I said, about 60% of all people with insurance. Now, there are three separate components that are important to how a commercial health plan actually decides what's covered and how they develop that coverage. And probably most important, how that coverage or the benefits that are provided, the services provided are paid for.

Most insurance companies have a clinical policy department that's responsible for driving coverage and patient eligibility guidelines. And what I mean by that is that these clinical policy professionals, and usually they're physicians. Oftentimes they're nurses. They take the responsibility



to review and digest all the literature that supports a new technology or a new service. And based upon that review, come up with one and critically, fundamentally, will we cover this service or not? Two, to what extent will we cover this service? And three, what are the patient eligibility guidelines or what's the clinical profile? What patient population will we cover under this policy?

And they do this in many ways. Many of them have internal technology assessment groups within the organization. For instance, Aetna has a very large, very experienced tech assessment group. And the principal objective of the tech assessment group is to make sure that of the new technology, both pharma, medical device, and new clinical services that are being offered, how they fit into the current policy configuration and whether it's actually something that's medically necessary or increasingly something that's medically beneficial.

Once the tech assessment is complete, the insurance company makes a decision, and yes, we're going to cover this, and no, we aren't. And if they do cover it, then it's important, it's very, very important for providers, as well as families, to make sure that they carefully review the policy language and the benefit language, because Cochlear implants and Baha technology both have distinct sets of service that often map very closely to benefits within the policy.

Then it's also critical to verify that those benefits are applicable to that patient within that patient's current medical condition. And that's where the bridge between medical necessity and policy language is made. Does the

patient, current patient in a clinical situation, will they benefit from this intervention? And if the answer is yes, the second answer is does the policy language, the specific language within the policy and the benefits allow them access to that intervention?

So verifying or obtaining benefits is often overlooked as a fairly simple and straightforward process. But I think any of you that have been involved in these kinds of efforts will readily admit that they are anything but straightforward. So the last part, then, is payment. How is payment determined? And there are a number of ways this is done. For hospitals and many clinics, sometimes individual clinicians in private practice, often sometimes payers want to pay them based upon a contract or a payment arrangement. And this is usually done, it's driven by many factors and it's a conversation in and of itself, but generally, a payer will look at the density of particular types of clinicians in a given area or geographical region, and if there is a lack of a specific type of clinician, they will generally agree to pay more, because they want to have that kind of medical expertise available. And oftentimes, they're willing to pay more if there aren't a whole lot of clinicians in the area. So there are lots of dynamics on how these break out. And again, it would be difficult to go into the details, particularly in the setting.

Then probably one of the most important concepts that's often overlooked, and we deal with it here at Cochlear on a day-to-day basis, is collections. Because oftentimes, the policy language certainly accommodates coverage for a particular service. The benefits is clearly in there. There's relatively reasonably clear idea of what the payment arrangements are,

what the contract calls for, but insurance companies will often withhold payment. And it's more than anything, it's a game, and the game is that if we can hold off paying long enough, and I know I sound cynical at this point, but I'm telling you after forty years, most of the insurance, I feel cynical about it. Oftentimes it's a game to withhold payment, because if the provider, if the clinician grows tired of the game and is wary of continually communicating the plan and asking for the payment, then the insurance companies will withhold it. And so that's money on the table that the provider community was not able to access. So I can't underscore the importance of collections enough. As I said at the top of the hour, Cochlear has a building component, and we bill for pieces of hardware, external components, and I have at least almost two full-time equivalents who are dedicated principally to collections. And I can tell you it's an ongoing going day to day challenge. And it's frustrating, particularly if you put everything in mind, the coverage is there, the payment is acceptable, and now actually getting the check becomes the challenge. So do not overlook collections.

Medicare is a federal program. And Medicare is not really an insurance system. It's a legal system based upon the social security act that was first signed into law by Lyndon Johnson back in the mid 60s. Medicare is the plan, but Medicare doesn't do this, doesn't provide these services all by itself. There's actually quite a vertical integration of payers seen as the acronym as the center for Medicare and Medicaid services. And it is an administrative body who reports to health and human services secretary. And it has responsibility for Medicare, Medicaid, and the state children's health insurance programs.

Underneath Medicare, then, as the actual insurance plan there are layers of contractors, and these contractors are private insurance companies who have agreed to contract with the federal government to interpret and pay claims and administer coverage guidelines and details. So Medicare currently covers about 40 million Americans. 85% of those are 65, age 65 and older. And 15% are disabled or have end stage renal disease. On an annual basis, Medicare processes about a billion claims every year. They manage 55 private contractors. As I said, the private contractors are actually the interface between Medicare as an administrative and planned body and the provider community and the community of Medicare beneficiaries. So oftentimes going directly to Medicare is very frustrating, when really the answer to some sort of problem's solution may be with the private contractor. And they pay, Medicare pays more than 1 million providers for services rendered to beneficiaries on an annual basis.

Medicaid is a joint federal and state program. It is the largest program providing health and medical services to America's poor. There are two, generally two buckets of recipients. Medicare insureds are generally referred to as beneficiaries. Medicaid recipients are usually referred to as recipients. So Medicaid's recipients generally fall into two categories. Either they meet income guidelines that are set on the federal level, but sometimes Medicaid on a state level will adjust or change those to suit its own state needs. And then the second bucket of patients are those with chronic medical needs. Currently, Medicaid covers almost 55 million Americans, which as you can note is much more than the Medicare program. Half of those are children, and a very small portion, about 10%

are patients over 65 years of age.

Medicaid has two delivery systems. And what that means is how the benefits are provided to the patients. One is traditional Medicaid, and that's a little bit different. Each state has a little bit different way of plying those benefits. And about 60% are provided by managed care plans, which are just what they sound like. They're local or regional HMO's that have agreed to provide Medicaid recipients with benefits they need through an HMO network.

I think we're going to have some time at the end of the session for questions, so let's forge ahead. I just wanted to take a couple minutes and talk about Cochlear's two products, the Baha implant and the Cochlear implant. In November 2005, Medicare published language that said that they now consider the ah what as a prosthetic implant, just like a Cochlear implant, and no longer do they consider it a hearing aid.

Now, the importance of this is in reminding you that the social security act or Medicare does not cover hearing aides by statute. And what that means is in the social security act language, it says specifically, hearing aides are not covered. So to be able to get Medicare to reclassify the Baha from a hearing aid, a statutory uncovered service, to a prosthetic was really a source of inspiration and joy for us here at Cochlear Americas.

Now, how will Medicare's change of heart impact the rest of the payer community? The Medicaid agencies in each state, it's a bit different. The commercial plans and, as we said, there are probably 6 hundred of them

around the country. We've noticed some immediate change in the commercial world in that some carriers who followed Medicare's billing guidelines, coding guidelines, and in some cases even their basement guidelines, very quickly adopted Medicare's new view of the Baha and began to change their language to reflect the fact that the Baha or the LSU integrated implant is a prosthetic and not a hearing aid.

Some insurance companies and, unfortunately, the larger ones, and that includes Aetna and United Healthcare, have covered Baha all along, but they covered as a hearing aid. On a practical basis, what that means is that hearing aides are generally covered in a policy through what they call a rider. So let's take Cochlear Americas, for example. If United Healthcare was our insurance company and we wanted Baha to be covered, United Healthcare would tack a rider on there that says we will cover hearing aides, including the Baha. But generally what that means is it carries a bit more of an increase in premiums.

So one of our principal focuses over the next 12 months is to work with Aetnas and United Healthcare, Humana, some of those others that view Baha still as a hearing aid, in spite of Medicare's change of heart to classify and treat it as a prosthetic.

To some degree, but it's very minimal. I have to admit that I was very pleasantly surprised that it was as minimal as it was. Some insurance carriers just simply do not cover Baha at all, either as a prosthetic or a hearing aid. And we've also got those on our radar screen.

In terms of professional services, and by that I mean, specifically, post-op fitting for the sound processor, currently no CPT code exists. And one of our objectives this coming year is to get a interest into the AMA for review for a CPT code specifically for the fitting of the sound processor, because Cochlear implants actually have a pretty well-developed coding and coverage protocol for postoperative services, and it can be easily understood since they've been around for a couple of decades. Baha, at this point, has no code. We suggest a miscellaneous code.

Other services, evaluation and rehabilitation, are amply covered by existing codes to evaluate Cochlear implant, as well as rehabilitate Cochlear implant recipients.

Cochlear implants, of course, have been around for over two decades now. The last few years there have been some refinements of coding protocol, but for the most part, there's pretty specific, pretty explicit coding codes in place that deal with not only the evaluation of candidacy, but evaluation of progress, as well as our rehabilitation and treatment. And I am happy to say bilateral coverage seems to be improving, and I've got a slide on this in a few minutes, but there seems to be a major improvement, a major leap forward in the payer world's willingness to look at bilaterals as standard of care and their willingness to cover it.

Let's jump into professional services, particularly for Cochlear implants. We'll do the same for Baha, and then we will also look at external parts and accessories. Programming and rehabilitation. Somebody told me, I started with Cochlear in 1997 and somebody told me very early in my

career that rehabilitation and programming is 20% of the cost, but over half of the outcome. And although I don't have any hard and fast statistics to prove that intuitively in the past 10 years, I've grown to accept that as face value. Rehabilitation and programming is really the smaller, the less costly components, but the importance of having access to adequate rehabilitation just can't be understated.

Most payers will include these benefits, and very rarely do we run into a payer of any kind, Medicare, Medicaid, or commercial, that explicitly excludes these. The problem sometimes is that they limit them very severely. And with most therapy, and you can see this in physical therapy benefits, occupational therapy benefits, and oftentimes payers regard these therapies as endless, a dark hole for constant feeding of funds and payment. But I think to some extent, that's beginning to loosen up. I've noticed recently that in some corporate policy publications, and that's relatively a new development, that many insurance companies will publish on their website a corporate policy, general coverage policy. And many of those are including the importance of adequate post-op rehabilitation. I've noticed that over the last 18 months or so. It seems to be the understanding of the importance of that seems to be growing.

Services without clinicians are generally not covered. I think that there are a lot of home programs that can -- that are available and can be developed, but at this point, mostly, and this applies to all therapeutic endeavors, therapeutic benefits, mostly they prefer that the patient be in the office with the clinician to receive that personal and face-to-face service. However, I think that there are a growing number of exceptions



that payers are beginning to think about that don't really require the patient to be in the office. Home therapy or home study, particularly for rehabilitation I think is positioned in the right way. Many payers would see it as not only an opportunity to improve outcomes, but also to reduce the cost associated with face-to-face or office visits.

And schools and camps include this, because I frequently get inquiries about that. They are generally not covered by most insurance companies.

In terms of payer break down, commercial generally limited, as I said. And most of the explicit details and the limitations are included in the policy language. And that's why it's important to spend the time to read it, and I'm not referring to you as the educator or providing clinician, but more importantly to the family or the recipient, to spend the time to read in detail what the coverage policy and coverage language provides. I think it surprises just a few minutes of effort, avoids what we call patient's prizes when suddenly they realize that they've had a service, but it wasn't really covered at the extent they thought.

Medicare doesn't really limit rehabilitation. They don't put limitations on services, except on occasion they will track, and if they have red flagged a provider, clinician, or clinic, they may track the amount of services, rehabilitation and professional services, and may make inquiries if they think that it's in excess or there has been -- you're thinking significantly large number of interventions.

Medicaid is historically limited. They generally want only what is required

to provide the minimal services. And so sometimes in some states it's very generous and they understand the importance, and sometimes it's merely a limitation developed by financial concerns. But still in all, in all three of those, with all three of those payer types -- commercial, Medicare, and Medicaid -- extension of benefits is possible. And this is generally based on progress or lack of progress. And this applies actually more to commercial plans or Medicaid plans. If you can develop a case, state an argument that these kinds of services are critical to the development of the patient, particularly children, their educational settings and home settings, definitely where safety issues are a concern, that sometimes -- and it works both ways. Sometimes significant progress and notable progress on the part of the patient is justification for continuing coverage, and sometimes lack of progress. It's all driven by each individual patient.

Some insurance companies have case management, and these are professionals. They could be nurses. They could be clinicians of other kinds who specialize in tracking high cost or what they call catastrophic cases to make sure that the patient, one, is getting everything they need, and two, that the costs of those services are controlled to the maximum extent possible.

But what I found in these endeavors to extend benefits is that patient involvement is critical. Family involvement is critical. The arguments that you, as a clinician or an educator, can put together to extend certain rehabilitative or therapeutic benefits are definitely important, and what the medical necessity depends upon. In the family environment, I think the family can provide input on how the child or the patient functions in a home

environment or how they function in a social environment. It sometimes goes a long way to getting insurance companies to extend benefits.

Programming for Cochlear implants. There are four codes. They've been around since 2003. There was, up until 2003, one code. And many of you that have been dealing with Cochlear implant rehab for awhile probably represent 92510. And 92510 is basically what they call a trash code in the industry. That's because literally every professional service that was available post-op for Cochlear implants was included. It was programming, there was therapeutic. There was evaluation. It was auditory rehabilitation.

The payer community, particularly the AMA and CMS, don't like trash codes, because it's not specific enough. So they began to dismantle 92510, and the first thing they did was to break out CI programming codes specifically. And so those codes on your screen are now used. 92601 through 92604. Now, they're also broken, 01 and 02, are for patients younger than 7 years of age, and 03 and 04 are for patients seven years and older, which of course includes Medicare patients.

I have underlined the word diagnostic, because I think it really speaks to a very interesting dynamic within Medicare coverage. When the social security act was written back in the 60s, audiologists were considered diagnostic, not therapists. Their principal job was to diagnose hearing loss or deafness. Speech language pathologists were considered therapists. Their principal job was to provide therapy to those people who suffered hearing loss. Excuse me. Or other communications disorders.

So consequently, Medicare kind of drew a very large black line between those two disciplines. Audiologists can not provide therapeutic services to Medicare beneficiaries. And speech language pathologists generally do not provide diagnostic services to Medicare beneficiaries. And so programming was kind of one of those services that straddles the line. Is it diagnostic or is it therapeutic? Well, it's basically both, because part of programming is to analyze the function of the Cochlear implant via the sound processor and then help to address or fine-tune or improve the program.

So in their wisdom, the AMA and, more particularly, the ashes editorial, CPT editorial committee inserted the word diagnostic in the descriptor. And what this did, it made it clear that this was mostly a diagnostic procedure, and what the outcome was that independent audiologists or audiologist in his independent practice can bill Medicare directly for programming without the word diagnostic, it would have become a speech language pathology program. And audiologists would not have had an opportunity to bill directly.

Programming codes, and this just further speaks to the slide, the previous slide, for those of you that would like to look into this further, programming can be billed by an audiologist in private practice if they have provider type 64. And the relevant manual, the on-line reference is right there on the screen.

The other part of that is that in order to allow services to be billed directly

by a clinician, there has to be a certain level of required physician supervision. And for programming, that's pretty minimal. And the other reference to that is also on this screen. So both of those speak to the fact that audiologist in his private practice can bill Medicare for programming services.

In January of 2006, there were four new codes. And this was, again, an extension of the CMS and the AMA's effort to try to eliminate 92510 as the trash or catchall code. Simultaneous with this publication, these four new codes, 92510, went on to its final reward and is no longer used or covered by any carrier: Medicaid in some states, but that's rapidly disappearing, and commercial. So these four codes actually speak to auditory rehabilitation and the evaluation of the rehabilitation needs. 92626 and 92627 are both notable in that they are the first time sensitive codes for audiology services that I have seen in quite awhile. In other words, 92626 can be billed for the first hour of services and 92627 can be billed for each additional 15 minutes. And it can be listed separately to the principal code, which is 92626.

So what this means is that these codes can be used to evaluate not only patient candidacy, but progress postoperatively, and they can be used to bill on a time sensitive basis, which is driven by the needs of each individual patient. So I think this was a stroke of genius by ash and the AMA and the CMS for driving this through.

192630 and 33 are specifically for auditory rehabilitation, pre-lingual and post-lingual hearing loss. The fly in the ointment is that because Medicare

does not consider audiologists as providing therapy, which is auditory rehabilitation, and only speech and language pathologists can provide these services, 92630 and 33 are not covered by Medicare at this point. Medicare does cover the evaluation codes we just went over, but 92630 and 33 are not covered, and what Medicare insists that you use 92507, which is treatment of speech, language, voice communication, or auditory processing. And this has been effective since March 1 of 2003.

The significance of this is that although there's been a constant drive to try to standardize coding, that in many cases due to the -- some of the fine nuances and details of the social security act and the coverage, sometimes coding for the same services is different. So let me reemphasize that. Medicare does not cover codes for auditory rehabilitation. Many commercial plans do. Many Medicaid agencies that are on the fee schedule, but for any kind of rehabilitation post Cochlear implant, Medicare insists that you use 92507. And keep in mind that it is a speech pathology code and not an audiology code.

Let's go on to external parts and accessories, including sound processors. There's been a lot of changes by Medicare recently, and I'm not going to delve into a lot of those, because I don't think it's been relevant to your needs at this point, but it's been certainly occupy a lot of my time lately. External parts and services, cords, cables, batteries, and repairs, oftentimes referred to as externals or peripherals, or parts, accessories, and services. Now anything needed to keep the device functioning or working is what we define as an external part.

It becomes particularly important after the warranty for many of these parts expire. Of course, there's no warranty on batteries. There are minimal warranties on some of the other parts and accessories. But it does become an important issue for many families and recipients. Probably two-and-a-half to three years postoperatively, they begin to wonder if they're going to be able to get covered that new sound processor upgrade or will I be able to maintain the volume of batteries that I particularly need for function?

Now, different payers cover externals in very different ways. Medicare and Medicaid are very predictable, but on the commercial side it's not that predictable. So I think the success in attaining coverage for these various parts really depends upon the level of knowledge that not only the center or the educator or the clinician has, but also the level of knowledge that's been researched and accumulated by the families of the recipients themselves.

Medicare, again, covers all services required to maintain function of the device. Now, that doesn't mean that they'll cover everything associated with a Cochlear implant. Certain cables are not covered. Certain pouches are not covered. Certain hifi and cables are not covered, because the bottom line for Medicare is that it has to be medically necessary to continued function of the device. So coverage is not really limited in terms of external parts and services by Medicare.

Medicaid, I'm sorry to say, some cover and some don't. Some cover adequately with very predictable policies and guidelines and some become

clinicians or if we happen to be signed up as a provider for that state where the recipients sometimes it's just basically a dog fight to get anything covered. But I think that that's changing. It's certainly better off than it was 10 years ago.

And part of the rationale that Cochlear had for approaching Medicaid agencies and becoming providers was not only to make sure that Medicaid recipients got what they needed, but also then we had a direct connection with that state Medicaid program. And we could begin to refine and fill out those coverage parameters so that they were very usable instead of perceived as nothing but obstacles.

Commercial/private insurance company. It's not an automatic benefit, but I think it's critical for families or recipients to investigate their commercial plan, because it may be just a phone call by the recipient or the family or by the clinician to the insurance company to explain what this is and why it's important to the continued function of the patient's Cochlear implant device or Baha device.

Sound processors. Of course, it's improving constantly. Does have a direct effect, each iteration, regardless of which manufacturer provides it. Each iteration does promise improved performance. And new sound processor can be classified as replacements or upgrades or additional processors. And that classification sometimes carries pretty significant implications in how coverage can be obtained or access can be made to the upgrade. And I'll get into that in a little bit more detail.



But payers' general reaction to sound processor upgrades or replacements is really very mixed. And it depends on many, many factors. Is it medically necessary? And that's defined by improved performance. It can be documented. And if you go down to the second to the last bullet that says useful life, medical necessity is sometimes defined as continual use of a piece of equipment for five to seven years, and at the end of that time, many insurance companies, including Medicare, we hope, in the near future will consider replacing a device with newer technology if it results in better performance or its met its useful life limitations or in the ideal circumstance, both.

Policy benefits, of course, sometimes in commercial plans will have specific language. It speaks to benefits associated with sound processors. And then oftentimes the cost of the new upgrade will have a significant impact on the negotiations or the willingness of an insurance company to cover.

Other factors we kind of went over. Useful life. I put in FM systems, because there have been some questions recently about whether FM systems are covered. They generally are not. And I think if there could be established or substantiated a medical necessity argument, improved communications, improved function, medically beneficial, if not necessary, it may be at some point in the future it will be covered. But right now FM systems are more considered communications devices than actually implants or technology or even an accessory necessary to continued function of the device.

Commercial plans. Again, the biggest unknown. Most people, unfortunately, assume that externals are not covered. And what my staff here in Denver tries to do is consistently counsel families and recipients that you need to at least investigate it, look into it. Look into your benefit policy booklet. Make a call to the insurance company. Ask if supplies or DME, which is durable medical equipment, or prosthetic devices, externals associated with prosthetic devices are covered. And I think it's critical, at least for, to some extent, for the piece of mind of the families to at least make those initial efforts to see if they're covered.

Other sources of coverage for Cochlear implant and Baha externals are homeowners policies, property and casualty policies, renter's policies, the VA sometimes will cover replacements or upgrades, and that's kind of a long shot, because unless it is directly associated, unless they're retired and it's directly associated with a service-connected injury, oftentimes the VA will consider a replacement or service, but you get on a priority list. For example, me, I was in the navy for four years from 1968 to 1972, and I could go to my local VA program and ask for evaluation for Cochlear implantation and they would be more than happy to do that, but I would be low, low on the list of priorities.

State vocation rehabilitation programs we have noticed over the years in some states are very willing to either buy repairs for sound processors or pieces of equipment or even professional services if -- there's a pretty clear connection between the provision of those items and improved performance and workplace in the ability to go back to the workplace and back to a job.

Then third or lastly, fourth source would be manufacturer extended service contracts, which I think all three manufacturers offer. Medicare, I think predominantly the device manufacturers are the principal providers to Medicare for externals, and that's because all three existing manufacturers can bill Medicare directly for these parts and pieces. Some clinics still will be willing to service a provider, but many hesitate. And frankly, I don't blame them. There are complicated billing guidelines that Medicare has out there. There's a cost of billing. Oftentimes clinics will have to hire or train or ensure that the billers have the tools to be able to monitor guidelines, particularly as the guidelines apply to prosthetic parts and externals and peripherals.

Cost of maintaining inventory sometimes has been quoted as a prohibitive factor. And then Medicare fee schedules. Often times the purchase price of an item doesn't equate in anyway, shape, or form with the fee schedule or the amount that Medicare will pay. So there are many reasons why clinics have sort of gotten out of the peripherals business.

We've assumed a role principally because we want to assist the centers and, more importantly, to ensure access through patient, Medicare patients through these externals. Now, one of the things that we've actually grown to appreciate over the last couple of years is the fact that there are no national Medicare policies regarding externals. Coverage is generally something that has been developed locally. So we have one competing manufacturer in North Carolina. One in California. And each of them approached their Medicare carrier in a different way and worked out

difference coverage parameters, dependent upon how that carrier wanted to deal with it. And that applies to us, too. We dealt with a local carrier here in Denver, and we're able to hobbled and cobble coverage parameters, even in spite of the fact there was no national Medicare coverage policy.

But the bottom line is that, like any provider, if we provide a service to a Medicare patient, then we are obligated by law to bill Medicare. So we assumed a predominate role in building these services for those three principal reasons. Nobody else would do it. It's too difficult and costly. We were able to deal with our local carriers. And that if we provide services, and what I mean by that is sell a rack of batteries directly to a Medicare beneficiary, then we are obligated, obligated to submit a claim for those services.

Generally, patients will have a co-payment or a liability when purchasing something from either the clinics or from Cochlear. Medicare, currently there are two ways in which a claim can be submitted to Medicare. One is a signed, and that means that there's no payment up front, that the patient calls, places the order, and the order is shipped and charges are billed to Medicare. Medicare usually pays at 80 percent, and then the manufacturer needs to collect the 20% from the recipient.

The other is unassigned. And that means that there is payment up front, and the recipient or the patient provides some sort of payment method at the time of order. Then we send a claim to Medicare on a courtesy basis, and then Medicare pays the patient 80%. Now, up to recently,

manufacturers had some discretion into whether we wanted to bill a signed or an unassigned. And we're currently going through some changes are Medicare. They want to reclassify how Cochlear implant and Baha externals are paid and covered. And they were kind of knee deep in trying to negotiate that with the federal government at this point. But as of this moment, the guidelines on the screen apply.

Medicare will cover sound processors currently, and these are the provisions that we outline with a local carrier. If the sound processor is lost, damaged, or stolen. And damaged beyond repair. If the sound processor technology is obsolete, then Medicare will definitely provide improved -- a better improved sound processor if the original one has been -- is obsolete, not only in terms of whether it's manufactured and sold, but also in terms of how effectively or efficiently it canning repaired. Medicare at this point is not -- does not cover additions or upgrades. The bottom line for useful life is that as long as the original -- the initial sound processor functions, that it would be -- that repairs would be covered, but upgrades would not.

Repairs to sound processors are covered. And what happens is that we receive the damaged sound processor. We send out a replacement of the same kind and type, and then we repair the damaged sound processors, submit a claim to Medicare, and get reimbursed for those repair charges. All other parts, accessories, and services are covered, as long as it's necessary, again, to the function of the device. And convenience items are not covered. And generally, the patients are billed at the time that they order those items.

Medicaid, this is really a function of 50 different ways of looking at externals. Very inconsistent. I would say half of the states have very clear and predictable and retrievable coverage parameters, but most of them are very controlled and limited in terms of their benefits or low payment for parts, accessories, and services. The rest do not have policies. I really haven't been challenged to refine or really develop into a user friendly process.

Many states adopt Medicare as their guidelines. Sound processors, replaced, lost, stolen, or obsolete. Sound processors are actually more medically available in the Medicaid world than Medicare. And Medicaid will look at requests to upgrade sound processors on a patient by patient basis. Is it medically necessary and is that very like Medicare? Is it based on improved performance? Useful life? Many Medicaid agencies will cover repairs, and mostly other parts and accessories or externals are covered. But again, they're generally limited. It's called utilization. Sometimes there are very strict parameters on utilization.

We have, here at Cochlear, a program that is designed to help patients who are not Medicare and Medicaid submit claims for sound processor upgrades and replacements. And we've had it for many years. We actually discontinued the program in mid last year, and based upon the human cry and the demand, we reinstated it in February of this year. And basically, it surged to allow us to take assignments sound processor replacement upgrades. If certain provisions, certain parameters are met. And those are if there is coverage within the policy, because we certainly

aren't going to sell the sound processor to an insurance company who doesn't cover the upgrade. And then there's -- they will apply in network benefits and they pay a reasonable amount. But there's a separation of activities and responsibilities for this program. Recipients and families are encouraged to do the coverage review and investigation to ensure that these benefits and policies are covered. And then it's up to the clinic. Now, that doesn't mean we won't help the recipients or families. Be more than happy to give them guidance and help them weed through the questions and particulars. But our policy is not to make the call or do it for them. It's really up to the family. Clinics and professionals, the only way that medical necessity, which is an integral part of any kind of service, can be established is through the clinics. The clinic has sole responsibility for determining if the patient is going to benefit, and if this is right for this benefit, and putting together the coverage argument, the medical necessity coverage argument. And this often requires documentation, clinical records, records of medical necessity, those kinds of things. And then once all of those activities are together, one, the recipient and family has determined there is coverage, the clinic or the professional has established medical necessity, we'll take those two concepts and Cochlear will go to the insurance company, ask for a preauthorization, and then bill the payer.

So what this does is this helps some families or recipients who can't afford the upgrade. Actually, we will take assignment on it and hopefully if everything works out, we can make sure that they have access to the technology they need.

Bilateral Cochlear implants. I have, I think, one slide, maybe two on this.

Preauthorization is not set by any stretch of the imagination. I think it can be challenging and I think many people in various regions of the country are finding that out. Specific exclusion, if it says we don't cover bilateral Cochlear implants in the body of the language, that's pretty hard to refute. That actually takes -- that goes beyond verification and clarification of benefits, and that goes into sometimes even a legal realm, but if there's vague wording that it doesn't say yes, doesn't say no, it really doesn't deal with it specifically, oftentimes that can be appealed successfully. But the critical component, again, is the patient and family involvement. The patient needs to study the benefits, study the language, make sure they understand how many appeals and what those appeals, how those appeals should be applied for or how those appeals should be submitted. And then you use all kinds of available resources. You use either the manufacturer's department's advocacy or consumer groups sometimes can help, and certainly legal aid programs can also be of benefit.

Participation by the family, again, is just critical. They don't -- they shouldn't rely totally on others. And that includes manufacturing programs. We can provide some information and some guidance and direction, but to totally rely on an outside third-party to obtain coverage is just not advisable.

What we tell them is do not be intimidated. If they say no, ask again and ask again until you've exhausted all of your appeal options. And always save an argument in your hip pocket. Never use all of the medical necessity arguments with the first letter or first appeal. And then just as critical is that denial should be appealed and appealed and appealed ad



naseum. You need to know why the request was denied. Who will review the appeal? I mean, is the same person who denied it originally going to review it on appeal? And how likely is it that they will reverse themselves? And then specific reasons. If the insurance company comes back and says it's for the covered, not medically necessary, then ask, what do you mean by that? What does not covered mean? What does not medically necessary mean? Because the audiologist or the physician has established the medical necessity at this point, and so I think those questions should be asked.

Now, if it's excluded, it's pretty self-explanatory. And in the policy, it says specifically, we don't cover. But the majority of denials usually are from not covered or the determination by the payer that it's not medically necessary. And those are definitely can be challenged.

Bilateral Cochlear implant coverage is getting much better. Interest is soaring. Surgeries are increasing. The number of exceptions is increasing. And what that means is that oftentimes, there is an exclusion, a specific exclusion in a policy, but through the persistence of the center, the persistence of the family, the persistence of the recipient, that oftentimes insurance companies will make exceptions to exclusions. And they will say, basically, well, we agree that this is medically necessary and we're going to cover it for this one person, but we're not going to change our general scope of coverage language, because we aren't convinced that it's standard of care for everybody. So we have noticed that the number of exception to his these exclusion is really increasing, and that's a good sign.

Some very large pairs of formalized coverage, and I'll explain more about that in the next slide. In June of last year and continuing through this month, some very large Blue Cross and Blue Shield plans have announced that they believe that bilateral Cochlear implantation is standard of care. Notably, the biggest Cochlear implant holding company in the entire country, anthem, also known as well point, that holds 16 Blue Cross and Blue Shield plans in various states and provides coverage for anywhere from 35 to 40 million Americans. Has announced that it is standard of care. HSCS, another Blue Cross/Blue Shield holding company, have also announced that bilaterals are standard of care. HCS -- HSCS has four Blue Cross and Blue Shield policies: Texas, Illinois, Oklahoma, and New Mexico. Individual Blue Cross and Blue Shield plans of Alabama, Florida, North Carolina, Massachusetts, and Tennessee also feel that it's standard of care. And one of the toughest nuts, no pun intended, in terms of HMO and the HMO world, Tufts health plan, also has announced recently it's covered. So I think there's a breakthrough in terms of commercial health plan acceptance of coverage. And I was frankly floored by the payers who were part of this breakthrough. Blue Cross and Blue Shield would have been the furthest from my mind as a payer group who would have accepted bilateral as standard of care and provided coverage details, coverage details and our policy language for them. I thought it would be Aetna or United Healthcare or some other large insurance company, but it was Blue Cross and Blue Shield. So go figure.

Still, bilateral Cochlear implants are case-by-case consideration, because although anthem says it's standard of care, it's still if that provision, if that

specific benefit is sold in the policies that are sold in each individual policyholder, like the employer group or labor union or mutual fund group. That's where the rubber meets the road. Blue Cross and Blue Shield can say, in a public forum, we feel that bilaterals are covered, but the rubber meets the road in the actual policy that covers that individual patient.

So the points remain the same: Persistence is the key to getting exclusions turned into exceptions. Medical necessity for that particular patient. Coordinated efforts along the patient, the family, and the clinician. And then looking at it in a very general way, there's a combination of arguments that need to be put together that generally will result in positive outcomes, and that's medical, educational, behavioral, legal arguments, performance, anticipated performance, because it's hard to test bilaterals without having undergone the procedure, obviously. But anticipated performance based upon prior performance with one non-medical impact. Education. Safety, workplace. Those kinds of arguments are often very, very important.

Our suggestions for obtaining coverage, and these are all they are is just simply suggestions. Coverage arguments or medical necessity needs to be developed based on each individual patient. And it needs to be a function of the clinic. It can not be a medical necessity argument developed by Cochlear or any other manufacturer. And we suggest that the initial implant always be mentioned. And there are various ways to do that. One clinic includes a copy of the op report in their preauthorization request, and that's their way of mention it go. They don't highlight it or speak to it specifically or repeatedly in any of their actions with the

insurance company, but they include the op report for that first intervention.

We speak to the age issue, because many insurance companies are more willing to provide an exception for children than they are adults.

Performance, particularly improved localization and safety, function in noise and the educational or the workplace, the argument, the bilateral are his not experimental. The technology is proven to be safe and effective and has been for years. The FDA said pretty clearly that they are exempt from investigational device requirements, and it's more an issue of standard of care rather than experimental investigational. And despite some of the protests from the payer world, there is a preponderance of literature out there regarding the advantage of buy neural hearing, not only bilateral Cochlear implants, but bilateral hearing aides as well.

But still, a work in progress. There's lots that needs to be done. The clinical and the research community must continue to prove the hypothesis that two is better than one. And so I think although well point, Blue Cross and Blue Shield of Alabama, Texas Medicaid, and all those payers that have shown a willingness to pay for bilaterals, we should not sit back on our laurels, that we just continue to strive to prove that by neural hearing is the best -- is standard of care and is the best state, the best outcome.

Increased public awareness. I think that more or less takes care of itself. When I first started for the company years ago, nobody really knew what a Cochlear implant was. And this is only 10 years ago. But now the conversation is more they understand what it is and they're very interested in how it works or what about bilaterals? Do they cover two rather than

one? And I've had these conversations in airports and on airplanes more and more frequently.

Coordinated public policy efforts. And I'll get into that in a minute, but Medicare is not clear whether they cover bilaterals. Medicaid, it's still driven on a patient by patient basis, and some states just simply can't afford and don't want to get into bilateral Cochlear implant coverage business.

Selected legal avenues. And I think suits by individuals, certainly not by manufactures, but by private entities or private individuals to sue their insurance companies I think sometimes will result in pretty positive outcomes.

And then most importantly, in my estimation, are consumer networks for mutual support. Putting people together to learn from each other to support one another in these efforts, because they are not easy. Sometimes it's very difficult and very frustrating. And we have had some success in referring people to groups, to families or individuals who have had success.

Medicare, in my estimation, does not cover bilateral procedures. I do know that Medicare has paid for bilateral procedures, but they certainly have not -- it's not a policy or standard of care at this point in anyway, shape, or form. But there are several anecdotal scenarios that I think will result in coverage of bilaterals. The first device was implanted prior to the patient's coverage by Medicare. That the patient continues to meet coverage

guidelines, existing guidelines. And that's kind of sad, because it means the patient is not doing well or their situation has deteriorated since having their first procedure.

And then there are patients who present with multiple -- with comorbidities or multiple problems, and sometimes Medicare will be very -- at least amenable and receptive to a second one, depending upon the medical necessity issue. Now, that kind of brings up something that is often lost in the translation when you're dealing with Medicare. Medicare provides services in two, basically in two ways: Delivery of benefits and services can be through traditional Medicare, which as most people recognize is the 80/20 policy, or through Medicare advantage, which is really an managed care and HMO way of delivering services. 80%, 85% of Medicare beneficiaries continue to rely on traditional Medicare to get their traditional Medicare plans to get their services. And so under the traditional Medicare umbrella, you can not preauthorize a service. Medicare assumes that you understand how Medicare works. They assume that you would not provide a service to a patient unless you knew that it was covered by Medicare. So they don't offer preauthorization.

15% of Medicare beneficiaries are covered by Medicare advantage, which again is the Medicare HMO or managed care plan. And they function as any other HMO in that there's a gate keeper and preauthorization required in the establishment of the medical necessity. So for Medicare patients who may be candidates, it's important to understand how their Medicare benefits are provided, because if it's traditional, then it's more of a roll of the dice and the hospital takes on that crap shoot, more or less, because

there's no -- there's no guidelines that say to Medicare -- who say that Medicare will definitely cover it. So you almost have to be willing to justify the implantation of the second device after the fact.

That's traditional Medicare advantage. There is possibly a preauthorization and sometimes I have heard that the Medicare advantage plans agreed to pay for a second one.

Resources. There's lots out there. None of them have a magic bullet. There's no cookbook recipe that will result in a positive outcome each and every time. This is still a case-by-case effort. Depends on the patient of the clinic and the payer's willingness. But Cochlear has ought to logic management services, which is a Cochlear benefit verification and preauthorization service, and we talked about it a bit at the top of the hour, and it's available at no charge. There are the companies, the other insurance companies -- or the other manufacturing companies that have similar services. LTHF in Palo Alto, California, has had done a good job of pushing check on here implant coverage.

OMS, otologic management service, again is a verification, preauthorization service. It's a no charge service, but it requires the center or the individual commission's agreement to participate. Traditionally, it has been good for small to medium sized centers, because usually large centers have the adequate resources or dedicated resources to obtain preauthorizations. We've expanded our own mess as a result of two influences. One, the Baha, bringing on the Baha technology. And although Baha, there have been a lot of very, very good developments, it

still is, basically, a dog fight for each and every case. And we've also wanted to make sure that we're in a position to support Cochlear implant bilateral coverage and the demand that we've seen.

We had partnered with a law firm here in Denver, Faegre and Benson, and right now I think we have seven or 8 cases they're reviewing for us. And these cases are specific exclusion to bilateral denials, to bilateral Cochlear implantation, or determinations that it's not medically necessary and the fact, in the face of the fact that it meets the FDA guidelines and meets maximum necessity requirements by the individual clinics.

We also have a Medical Advisory Committee that helps to advise us on issues of medical necessity and coverage. And with the helps of those two partners, OMS has really been doing some outstanding work. I think it's a great tool and it's been wonderful to have it around for a couple of decades. But I think with the addition of these two partners, we're going to do many good things in the future.

In terms of politics and advocacy, that's basically one slide. Years ago, I was asked, why is reimbursement for Cochlear implants so difficult compared to other otolaryngology or otology procedures? And I came up with these four reasons, and I think to some extent they still apply. In a very general sense, the decision makers, the policy-makers, those people in the clinical policy departments I talked about early on in commercial health plans really consider hearing health to be a social issue and not a medical or health issue. And I think there have been great strides recently on addressing those in establishing the bona fides, if you will, that hearing



health deserves allocation of resources. Even Medicare admits that there are three areas that consume a lot of their resources and that's cardiology, mobility or orthopedics, and hearing loss or hearing issues.

So even the largest payer in the country admits that this is an important issue. But still, I believe most decision makers still see it as a cultural distinction and not a healthcare decision. Even though the volume of surgeries is growing dramatically, it's still, in terms of other procedures, other surgical interventions, there's a low volume, and I think that will be addressed as time goes on. And in the fullness of time, but right now, even though it's been around for a decade, a couple of decades, there's a huge, unmet need out there. Some players, and this always blows my mind, but some pairs still see it as experimental or voodoo technology. and when we find those, we're on them, because that's ludicrous to have hidden under a rock for 20 years not to understand what Cochlear implants are and the outcomes they provide or other implantable hearing technology.

Then I think most importantly is lack of aggression by the Cochlear implant community. And I would now include the Baha community in that statement. And notice I'm not saying lack of aggression by the Cochlear implant manufacturers or the technology manufacturers or the professionals or the recipients or the advocates. I mean lack of coordinated aggression by all of us. And sitting down together and deciding what we want to accomplish and then working in tandem to accomplish that. Oftentimes the arguments are who is responsible for improvement, and I think it's all of the affected parties and the stake

holders.

I believe Donna has left us, so let me just leave this slide up for a few moments so you can see when the next HOPE on-line seminars are scheduled. Here is a couple of features for HOPE e-news that I can you can probably look at when you look more closely when you download the slides after the session. Here are contacts. Cochlear's impact. Feedback from the Hope Program, and for specifics or questions you have on the seminar, you can certainly -- more than happy to contact me directly.

I'm sorry for the delay. I think I've messed up here. Anyway, are there any questions that I can answer for anybody? I'm sorry, folks. I think I went one slide too far. It looks like I can't retrieve those slides. I'm not sure that I'm still on, but if you have questions or comments, please feel free to e-mail me at my e-mail address or call at 800-523-5798 and ask for me, John McClanahan. Again, I apologize for the abrupt termination of the presentation. And I thank you all for your help or your attendance. And again, if you have questions, feel free to give me a call or e-mail me. Thanks very much. Bye-bye.