Health Insurance DOES Cover Cochlear Implants, in partnership with American Cochlear Implant Alliance

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- [Christy] It is my pleasure to introduce Donna Sorkin, the executive director of ACIA. She is going to present along with Dr. Terry Zwolan, today on health insurance, and how it does cover cochlear implants. I'll pass it over to you, Donna.

- [Donna] Thank you so much, Christy. Thanks to the whole team from Audiology Online. We love presenting with Audiology Online. Our session today is part of a series that we're doing on helping your patients understand benefits, and addressing their fears, and we're covering four topics that are of interest. I'm so pleased to be joined today by Dr. Terry Zwolan, whose director at the University of Michigan Cochlear Implant Program. So you many wonder why there's another organization in hearing health when there's already a number out there. I want to convince you that we are needed. We are a membership organization that's focused on cochlear implants and access to care that is our special space. We are comprised of audiologists and physicians, speech pathologists, educators, and others on cochlear implant teams, as well as consumers and parents and advocates, and an increasing number of Veterans who join us to get information on hearing health. We have a website that's designed for those both in, and outside of the cochlear implant field. And we really work to be highly collaborative with other organizations including Audiology Online, and we welcome your involvement. We've listed our website, and Facebook, and Twitter up there for you to take a look at.

Our mission is to advance access to the gift of hearing through cochlear implant, and we work on research, advocacy, and awareness, and specifically address those factors that contribute to the underutilization of cochlear implants. We know that only about 7% of adults who could benefit are using cochlear implants, and so that's really an area that we're spending a lot of time and effort on. We look at improving awareness, about candidacy and outcomes, and our objective today is to share information to help patients who may benefit move forward. In the U.S. right now only about less than 7% of adults who could benefit actually have a cochlear implant. In some surveys that we

did we found that the perceptions that adults themselves have even when they know about cochlear implants, and that they exist often contribute to long wait periods, and reluctance by some to ever move forward. One of the four topics that we learned is a barrier is that the perception that cochlear implants are not covered by health insurance, so that's the purpose really of walking through this particular course. And then the other ones we're covering are outcomes, and how do I know I'll gain more than I lose? The surgery which is sometimes a reason that people are reluctant to move forward, and then a bit on the cochlear implant rehabilitation process for adults. Many factors contribute to underutilization of cochlear implants. The main reason is a lack of awareness about candidacy and benefits. We find then even audiologists are often unaware about CI. There's a lot of resources that can help on our website, and the courses in this series can also help. And not moving forward because the perspective about insurance is one major reason. In fact, it is the most common inquiry that we have into ACI Alliance. We get phone calls everyday almost about insurance issues. We get emails and people go on the website, and then send us information that way.

I had a call, actually, yesterday from a friend of an adult who had a cochlear implant, and the person had lost her sound processor, and the question was how does she get a replacement? She can't pay for it. The person was covered by Medicaid, but they had no idea that that was the first place that they should look. I think part of this lack of understanding is due to the fact that in general hearing aids are not covered by health insurance, so people make the assumption that cochlear implants aren't covered, but they're not the same. It's a prosthetic device it's covered in a different way, and that's the first thing that people have to know. These are some very common inquiries that we get. How do I pay for a cochlear implant? The assumption that it isn't covered. How much will it cost? Which is very difficult to answer it's like asking someone how much will my heart surgery cost? How do I know if my insurance covers? How do I tell what my insurance covers? What will be my co-pay? And what do I do if I determine that my insurance carrier says it doesn't cover cochlear implantation? So we're going to

answer all of those questions today. Coverage has evolved. In the 20 years that I have been working in the field of cochlear implants we have moved from there being not very consistent coverage to finding that most health insurance policies now cover. What does vary is the way the policy covers cochlear implants. We're gonna talk a bit about that. It's important to know that public insurance covers, so Medicare, Medicaid everywhere for children, in about two-thirds of the states for adults, Tricare, and the VA all cover. Private, and state employer plans about 90% we find cover cochlear implantation. It's important to always look at the specific plan to confirm that it covers, but don't assume that if there's no specific mention of cochlear implants as a covered service that it's not covered because not every plan mentions every intervention, and every healthcare service that they cover. So you have to delve a little bit deeper to have a sense of that. And if it isn't covered and you find that out don't give up. We're gonna talk about how to address that later on in this course. So I've put this continuum of care up there.

This is actually something that Terry Zwolan and I did in 2014 when we were just getting this organization off the ground, and people had a lot of questions of what the process looked like. I find it's useful to come back to it so that you understand that we're talking about the whole continuum of care for cochlear implantation, and that whole continuum of care needs to be addressed. It's typically all covered by insurance. Just like any other surgical procedure that someone has done the whole continuum of care is covered. So this is just to show you that there is both audiology services and medical services, and there are services that are carried out before the actual surgery. And then we get to the surgery itself, which is what people typically think, ah, that's what I'm talking about. We're talking about the surgery, and the device, but, obviously, that's just one piece of the whole process. And then medical appointments that follow. The audiology appointments. Very important the rehabilitation for children and adults. And device maintenance what do you do? Like the call that I got yesterday the person lost their processor what do you do with that? Yes, that is covered by insurance. So this is all on our website. There's also an interactive version on the website with more

description of the various steps. So just to take you through all the different ways that we cover cochlear implants. Medicare, of course, is a health insurance program for people over age 65, and certain younger people with disabilities. It covers for those who meet the Medicare candidacy criteria. It's important to understand that they are more restrictive than the FDA and they can do that. Currently, the Medicare guideline is 40% words in sentences, whereas, FDA is higher than that. ACI Alliance is working with Medicare to expand this. Terry Zwolan is leading the charge on this. It also does not cover bilateral severe to profound, which FDA covers. That means it doesn't cover SSD. Right now, recently, FDA indicated that they would include SSD in the guideline, but Medicare has not changed on that. And the audiogram must touch profound as well. Now if someone has a Medicare Advantage Plan, or Part C, it may be the case that they would have Medicare coverage through either HMOs or PPO plans because they're different, and the plan can determine what the premiums are, what the co-pays are, and what decisions they want to make about paying for treatment. It may have a different criteria for cochlear implant than a straight Medicare plan. So it's important to look at those specific guidelines regarding, for example, whether they cover bilateral CIs, whether they cover single-sided deafness because they may have a different criteria.

The processor upgrade portion of it may also be different than Medicare. So the other plan I wanted to talk about is Medicaid. Medicaid is health insurance for people of all ages whose income and resources are insufficient to pay for healthcare. Medicaid was actually begun in 1965 as part of the Great Society programs that were carried out by President Lyndon Johnson. People sometimes think they're the same, but they're separate and they operate differently. Medicaid is actually a joint program state and federal. It's funded primarily by the federal government. It's carried out at the state level. States all cover for certain populations. I'm gonna talk a little bit more about that, but the way they cover may vary. Medicaid is a huge funder of healthcare. It's $1 of every $6 of national healthcare expenditures in 2018. The thing to understand about Medicaid is that there are optional services and mandatory services. Under the original

Medicaid law passed in 1965 it listed what they considered to be mandatory services, and I've listed them there. And optional services was everything else. It's so important many important services are considered optional under Medicaid. That means the state can decide whether they want to cover or not, and speech, hearing and language disorder services, and prosthetics are all part of that optional category. So states can decide whether or not they want to offer things in the optional category. What happened right after Medicaid was passed in 1965 was Congress realized that states were carrying these laws out differently, and depending on where someone lived a child may not be able to have access to specific services, and so they passed a new law in 1967 that added something called EPSDT to the original Medicaid law. And it said that there were special needs of children who were low income and that that they were at risk, special risk for conditions, and that could impose lifelong disabilities. So Congress said that they had to look for children beyond adult treatments, and issues that impacted on the growth, and development of children had to be covered for states. And that means that hearing services including cochlear implants are covered for children everywhere because of that aspect of federal law. And that, in fact, is the case.

Cochlear implants are covered for children in all of the states. It's interesting that about half of our surgeries in the U.S. for cochlear implants are actually funded through Medicaid. The states can determine specific candidacy criteria. They do vary. In general they follow the FDA, but it may take time for them to change, and they cover the entire continuum of care not just the surgery. What we find sometimes is there may be stated limits on the number of therapy sessions, but clinics can also request extensions and service, and they're usually successful. The place where we see the biggest problem is in sound processor upgrade replacements. These under Medicaid can be extremely difficult. We may see them saying that they can only be replaced if they're at least 10 years old, and they're obsolete and can't be repaired. And on the adult side states can decide if and how they wish to cover adults. We find that about 60% of states cover adults for cochlear implants. Military insurance covers. Tricare for

eligible individuals, and VA covers cochlear implants for Veterans, and family members who meet specific VA criteria. In general it has to be a service-related hearing loss, or if they're under the VA's care for other health issues they can be covered. Family members caring for a Veteran with a disability can be covered for a cochlear implant. They do have to have a child with hearing aids. What we find is that there's variability in the way referrals are made for Veterans who could benefit across the United States. Some of the hospitals are quite good about it. Others not so much. Private insurance is, of course, the main way we receive our health insurance in the United States. 56% of individuals in the U.S. are covered by private employer plans. The majority cover cochlear implants, but there may not be specific mention in the plan, and private plans typically follow the FDA guideline. So it's important to contact your insurer to determine the coverage, and clinics and manufacturers have staff who can help, and they do help.

Occasionally we find specific exclusions for cochlear implants, and advocacy can be helpful in removing those. We're gonna talk more about that. The last one I wanted to mention was Affordable Care Act, ACA Marketplace Plans, also known sometimes as Obamacare. They are still offered. We have found that they have become quite expensive because of the lack of support from the current administration. They are sometimes a means of getting coverage if someone's plan doesn't cover, and it's important to check the specific Marketplace Plan before buying one if you're doing this for coverage for cochlear implants. Typically, there's multiple plans. We worked after the ACA was passed, we and our state champions and most of the states worked to include coverage in the plans. So most of them do cover, and we find it's a great option for some. I know people who have bought plans there because their regular insurance didn't cover. Procedures for determining coverage this is where I am turning the floor over to Terry Zwolan. Terry is a professor and director of the Cochlear Implant Program at University of Michigan, and she has been involved in this field for a very long time. She was a founding it should be co-chair of the organization when we first

got started in 2012, and she has served out her time on the board, and now helps out in other ways. I'm honored to turn the floor over to Terry Zwolan.

- [Terry] Thank you Donna. It's really my pleasure to be part of this, and to be collaborating with the ACIA, and also with my good friend, Donna Sorkin. I've been involved with implants for a very long. So my task here is to try to make sense of this complex insurance issue that cochlear implant programs try to navigate with their patient's best interest in mind. So we're gonna talk you through what happens with the patient when they're trying to seek a cochlear implant, and also try to seek payment for the procedure from their insurance company. So, fortunately, implant clinics typically employ an insurance preauthorization specialist. A lot falls on the audiologist, and quite a bit on the surgeon, but thank goodness for the specialist who can really guide us, and lead us through this process, and help navigate patients through this process as well.

So where we first start is our patients often require a referral for all visits related to the cochlear implant. So even for their initial appointment our front desk knows that they need to check benefits, and if the patient needs a referral they need to let the patient know, and a lot of times will contact their primary care doctor to try to get the referral for them. Implant programs will vary in the amount of help they'll be able to provide to patients in obtaining referrals and other information, but certainly they need to be in tune with the needs of the patient. So some of the coverage it can really get complicated, and patient's policies will vary greatly. So these are the steps that we're going to take you through, which are all the possibilities that happen once we examine the patient's policy. If we look, one of the first options might be that the most common one is that the insurance company requires that the device be FDA approved. And that's very easy to check to see if it's received FDA approval. And then some of them might require that the patient meet the FDA stated indications for that particular device. So FDA indications typically follow a lengthy clinical trial where the device is implanted in several individuals. The FDA looks at the outcomes, and then they come up with

indications or criteria based on that clinical trial. And these indications typically include statements both about the degree and severity of the hearing loss as well as statements about the speech recognition, or benefit that the patient can have from hearing aids. The complexity of this is increased by the fact that the indications for the currently available devices vary in regard to these factors, so we're gonna take a quick look at the FDA approved indications that we have for currently available devices. And you'll also see that there are typically separate indications for children as well as for adults.

So I've got them plotted out here on this slide. I've got them divided according to advanced bionics, cochlear and MED-EL. The top row is for adults, and the bottom row is for children, and you can see how they vary among the two populations as well as among the three different devices. So, for example, Advanced Bionics, their current one is post-lingual onset of bilateral severe to profound hearing loss, which is a little bit stricter than cochlear, which requires a bilateral moderate to profound hearing loss in the lows, and profound hearing loss in the mid to high frequencies. And then we have MED-EL, which listed as bilateral severe to profound. And they even get more specific about the pure tone average. If we look at children they vary from device to device as well. We've got AB with bilateral severe to profound hearing loss. Cochlear is spread out depending upon the age of the child with being profound if they're less than two, and severe to profound if they're older than two. And then MED-EL, again, has a little bit more specifics in terms of the threshold and its certain frequencies. So that's the FDA labeling in regards to audiometric thresholds, and then on top of that we also have to look at their speech perception scores. So those vary as well. We might see something that lists less than 50% with a specific mention of a test such as the HINT sentences. In the best aided condition cochlear says 50% on sentences in the ear to be implanted, but less than 50% in the best aided. So theirs are a little bit less strict. And then MED-EL would say less than 40% on HINT sentences in the best aided condition. In children there's a little bit more consistency, although it still varies. The word score that they require older children to have, typically, needs to be less than

either 20 or 30% on word scores. If they're older we might be able to test them on sentences. One thing to note is these were created several years ago, and in terms of contemporary care they're all rather outdated. So the good thing is that we're actually able to look at these indications, and even the FDA recognizes that sometimes their indications don't apply to everyone, and we can't sort of put everyone into these certain criteria. So if a patient does not meet the FDA, or the insurer's indications, you can consider providing the implant off-label. And the reason they refer to it as off-label is because, actually, the FDA indications, or approved indications for a device are actually printed on the label of the device's box. So if you're going off those labels, or off those indications it's considered off-label, but the FDA recognizes that some patients should receive a product even though they don't meet those approved labeling, or indications. So if you go to the FDA website you can see that they indicate that good medical practice in the best interest of the patient require physicians to use legally available drugs, biologics and devices according to their best knowledge and judgment.

So I like this because it brings in clinical judgment. So we're able to look at the FDA indications, but we're also able to look at the patient, and determine if they don't meet those indications then maybe they still are a good candidate for a cochlear implant. Clinics can actually cite this information if, for example, an insurer says that you need to follow FDA indications we can say that the FDA says that we can use off-label as long as we follow their guidelines in terms of this, as well as we can ask special permission to do so. If they require us to follow FDA indications, they might state that it has to be an FDA approved device, or sometimes they might have their own indications, and this is actually becoming more prevalent than in the past. It used to be we would look up an insurer's benefits, or a beneficiary's benefits and it would state must follow FDA approved indications, but a lot of times now they'll have their own indications, and those indications might be stricter, or they might be more lenient than those of the FDA. So a good example of this is Medicare. Medicare is stricter in terms of speech recognition than the FDA indications because they require a sentence score

of less than 40% in the best aided condition. We saw that on some of those FDA approved indications we could go as high as 50 or even 60% on speech recognition. Some will require a pure tone average of 70 dB, which is different than simply stating a moderate to profound sensorineural hearing loss, and some might require a score less than 50% correct. And they might state that it's in the ear to be implanted rather than best aided. So it's stricter because it's a lower score, but it's more lenient because they're not basing it on best aided. So it's really looking at fine details of the wording of the insurer's indication of the patient that we want to recommend the device for. So it's really essential for the implant center as well as for the patient to be aware of what their benefits state, and the criteria that that patient does, or does not meet. It can get especially tricky because some insurers may or may not allow you to preauthorize.

So by preauthorize it means almost asking for permission. So if I preauthorize I'm gonna send you my data, and I'm gonna ask you for permission, and if you preauthorize it means that you've looked at my information and said, yes, we'll pay for that. One of the most prevalent ones that don't preauthorize is Medicare. So straight Medicare does not preauthorize a cochlear implant surgery. They publish guidelines which are referred to as the National Coverage Determination, or NCD, and they state that all of those selection guidelines must be followed if a clinic is to receive payment for the device that was provided under Medicare coverage. If the guidelines are not followed the implant center places themselves at risk for denial of payment, so, for example, we can't preauthorize if somebody doesn't meet those criteria, but we still provide them with an implant. If Medicare audits us later on they could say we're not going to pay for that, and they might fine us a large fine for going outside of those guidelines because we're obligated to follow those guidelines. So if we encounter a Medicare patient who doesn't meet the Medicare guidelines, one option could be that we could contact our local Medicare administrative contractor, or our MAC, to seek approval when someone does not meet those indications. I think clinics really vary greatly in terms of their ability to seek approval from their MAC. If a patient doesn't meet criteria I would say most clinics if a patient doesn't meet their criteria then they

recommend that they come back in six to 12 months, or sooner if their hearing drops in order to try to catch them as soon as they do meet Medicare's criteria. Donna had mentioned the Medicare Advantage Plans. Sometimes they might be a little bit more lenient, so patients have an opportunity to enroll in the Medicare Part C plans about once a year. So one of the options might be that a patient can look into a Medicare Advantage Plan if they're not meeting their straight Medicare NCD. Like Medicare some private insurers will not preauthorize, and will not consider special cases, and that makes it very hard for an implant program if they won't preauthorize because we have to go back to the patient and just say, I'm sorry, your insurance really won't even let us ask for special permission to go outside of their published indications. And if we did do that like Medicare that insurance company can ask for copies of our records, and if they find that we've implanted someone that doesn't meet their indications then they'll deny payment, and likely we put the patient at risk for having to pay for that expensive procedure.

We might have an insurance company that says we need to review all the test results before we'll preauthorize. That's not a bad thing. It's sort of a safety net for all of us because then it's really up to our interpretation, as well as their interpretation to make sure we're all on the same page. The only thing is it does, typically, slow it down because you need to have all of the tests that they require. You need to send them to them so they can review, and it just slows it down a little bit, but we might need to set things like the medical evaluation, the audiogram, the CT, and the MRI, speech and language. Our Michigan Medicaid is very good with their coverage, especially of our children as well as of our adults, but they do require a review of the test results before they'll provide us with preauthorization for an implant. And as I stated earlier some insurers may or may not consider special cases. If they won't consider special cases we're stuck between a rock and a hard place. If they have Medicare they could consider the Medicare Part C plans. If they have private insurance, sometimes they have the option of at the time of enrollment switching to a different insurer that might cover cochlear implants. We have had some patients successfully do that. At time of

enrollment they wait. They switch to a different plan that does cover cochlear implants, or one that might consider off-label, and they've had good success that way with getting coverage. If they will consider special cases, if they receive a denial because they don't meet those traditional indications, the patient can work with the clinic, and they can appeal that denial. Sometimes it needs to be in writing, and sometimes it might be a peer to peer review, and we'll hear a little bit about that more later on. So the insurance approval process if it is denied a lot of times the insurance company will publish their benefits online, which allows for a quick review. So our insurance specialists will look at the benefits, tell me what they are, let me know if the patient meets those benefits, and then we can establish that quick review online. If they require a review of records, or if they won't accept an online request that might slow it down, but, typically, we are able to preauthorize, or determine benefits coverage in about two to four weeks for a traditional candidate. If we have a special request for someone who doesn't meet the published indications of the insurance company then it will typically take a little bit longer than two to four weeks.

So one of the important questions that we receive from our patients is, well, how much is this going to cost? And what are my out of pocket expenses going to look like? That information often depends on the patient's plan, and it also depends on the patient's access to either supplemental or secondary plans, especially, if the patient is enrolled in straight Medicare. So a lot of times patients are confused and they say, well, I'm not sure if what I have is a supplement, or a secondary insurance. As we know supplement is additional insurance, typically purchased to help pay for services. So if someone has straight Medicare, Medicare will cover 80%, and if they don't have any other insurance then they're responsible for that 20% coverage. If they have a supplement then typically the Medicare supplement will pay 20% of the allowed cost, while Medicare covers that 80%. For an expensive procedure that 20% can be quite large, so it's really helpful if a patient is going to move forward with a cochlear implant for them to have either supplement, or secondary insurance to help with that 20% coverage. A lot of times with supplements they'll say we'll pay it if Medicare will pay it. If it's covered by

Medicare we'll cover it as well, and they might not require preauthorization. Typically, that goes through pretty quickly for a patient. If someone has secondary insurance that means that they have two insurances. So that might be if your spouse has you covered by their insurance, and your employer covers you as well, you'll have two insurances and you typically have to choose which one's your primary, and which one's your secondary. So if someone has secondary insurance then it might require separate preauthorization because it is a separate plan. That might slow it down a little bit, but, typically, as Donna indicated a lot of insurance plans cover cochlear implants, so if someone has two insurances, we're typically pretty certain that they're gonna be very well covered for the procedure as well as all of the postop appointments. And, sometimes, the supplements in the secondary insurance might help cover the deductibles, the co-pays, the co-insurance, all of those things that come into the out of pocket expenses. A lot of patients don't know what these mean.

So they'll say this cost me $1,500. And we'll say, well, that's due to your insurance plan, and that's probably your deductible. And then we look it up for them, and we explain to them the deductible is really the amount that the patient has to pay for covered healthcare services before the insurance plan will start to pay. So if the patient's plan has a $1,500 deductible that means that any healthcare expenses they have, typically, at the beginning of the year will have to be covered by the patient until they meet that deductible. So they might have to pay $1,500, but after that then they share the cost with their insurance plan. Some plans might have a separate deductible for durable medical equipment, so they might have one for their appointments related to the cochlear implant, and then when they go to do an upgrade they find that they have a different deductible for durable medical equipment. Some patients might delay surgery until after their deductible has been met, or they might have a bilateral within the same calendar year, or in the same year of their plan so that they don't have to try and meet that deductible a second time. Co-insurance is that amount of money they might have to pay after they've met the deductible, so it gets even more confusing, but if we think about once that deductible is paid then they're sharing it with their

insurance company, so it's considered co-insurance, and it's usually figured as a percentage of the amount that the insurer will allow to be charged for services. For example, if they've paid $1,500 in their deductible after that when they go to see their doctor they won't have to meet that deductible any longer, but they might have to share the insurance cost with the insurance company. So after that the plan might cover 70% of the cost, and the beneficiary might have to pay 30%, so they're sharing that cost for those appointments.

Co-pays are very common, and they're sometimes collected in the office itself, and that's a fixed amount that the beneficiary pays for a healthcare service. Usually it's paid when they receive the service. We all know sometimes we check out at the doctor's office, and they'll say, okay, so your co-pay is $25, and we hand them our credit card or write them a check, and sometimes they'll vary depending upon the type of service. They might charge $25 for an office visit, and they might charge $100 for a more expensive visit such as an emergency room visit. How it works is that the plan determines what the co-pay is for these different types of services, and when they have one. Sometimes the office visits might even vary, so if you go to see your primary care doctor for a health maintenance check there might be no deductible associated with that, and that's probably because insurance companies want us to have those health maintenance checks, whereas, if it's an appointment where you're not feeling well, and you need to go see your doctor then you might be charged the co-pay outside of that well check. And some patients might have a co-pay before or after their deductible has been met. It really varies from plan to plan. So now we see how it's so hard for audiologists to try and give insurance advice to our patients because there's so many different aspects of it. Another thing that we need to consider as a cochlear implant program, we have patients that come from all over. We have some from out of our state. We have some from several hours away within our state, and we've got several patients that come to us from different countries. When a patient presents to us they might sometimes have an insurance that's out of network, and that means that if they're out of network it means the doctor or the facility providing the care does not

have a contract with that patient's health insurance company. So, typically, if we have someone whose from far away we're considered out of network. And out of network coverage varies among plans. So, sometimes, a more expensive plan like a PPO might be more lenient with you going out of network, where an HMO might be stricter where they won't pay for coverage if you go out of network. This can be problematic with a cochlear implant really depending upon the patient's plan, but, typically, the cochlear implant program will work with the patient's plan to get coverage for out of network services. This is particularly important if a patient is limited. Let's say they have an HMO, and they're up in the Upper Peninsula of Michigan, and they don't have access to a cochlear implant program in their immediate area we can talk with their plan, and seek preauthorization for the implant because we tell them there's nobody in their network that provides a cochlear implant. We've also had some of our patients who've switched plans, and then it turns out that their new plan has a different provider that's a network, and we can appeal that, and say that they've established care with our center, and they would like to still have coverage through our plan, and we've had good success with that. It just means extra work, but it's important to note if there's out of network because, typically, the out of pocket costs for the patient might be higher when they're seeing an out of network provider.

So it's another important thing that we pay close attention to. So with all of these, sometimes there are roadblocks that might prevent, or make it much harder for a patient to receive a cochlear implant. No insurance, in this day and age it's kind of sad. It happens, it doesn't happen all that often, but if a patient has no insurance there are some things that we can look into, and we'll talk about that in the next slide. There might be a specific exclusion in the insurance policy for a cochlear implant. Where we've seen this is for smaller insurance policies. It might be a very small company, and they've purchased a very limited plan, and in that plan it might specifically state that they don't cover cochlear implants. We might receive a denial because they say it doesn't meet the insurer's requirements for a cochlear implant. We might have to go through the appeal process with that person if it's been denied. There are some state

government options available that will help with these roadblocks, and there's some other advocacy that might help. So what happens if someone has no insurance? They could purchase an Affordable Care Act Marketplace Plan, but before they do that we want to make sure that they look at that plan to ensure that cochlear implant is a covered benefit under that plan. And they should really look at their co-pays, and deductibles, and how much it is covered before they go ahead and purchase the Obama, or Marketplace Plan coverage. They could additionally explore the ability to participate in a disability evaluation under Social Security. I would refer you to the ACAI website. There's a great deal of information there to sort of help clinicians and patients navigate the disability evaluation under Social Security. It does apply to both children and adults. There are very specific criteria, but, typically, if a patient qualifies for a cochlear implant they will qualify under the disability evaluation, so it's important for clinicians to be aware of that information.

When we find someone that does this we refer them to their local Society Security field office, and we work with their state agencies so that we can help provide the information about the hearing loss to help them obtain coverage under the disability evaluation with Social Security. As a last resort patients can pay out of pocket. Typically, an implant program, and this often happens for someone that comes to us from a different country they're willing to pay out of pocket, and what cochlear implant programs, or, actually, hospitals in general tend to do is offer a reduction in the cost, sometimes as high as 40, 50, 60% for paying cash for services. And, lastly, if there's an exclusion ask your employer to work directly with the insurer to remove the exclusion, or discuss it with them yourself. You can determine if your state has legislation requiring insurance coverage for cochlear implants. You'll hear from Donna on this. If it's a child, determine if your state covers children under Medicaid regardless of family income. In Michigan anyone can enroll in Children's Special Healthcare depending upon the diagnosis, so anyone that qualifies for a cochlear implant can enroll in Children's Special Healthcare. Again, explore that disability evaluation, or file that important appeal with your insurer. And before I hand it back to Donna, one quick

mention is the clinic is usually working with insurers as well as with the implant manufacturer to try to get the important sound processor upgrades. Policies vary greatly, but all typically require a letter of medical necessity from the implant program, typically needs to be signed by the implant surgeon stating that the upgrade is medically necessary. To determine if an upgrade is covered you can check the benefits of your patients simply looking for HCPCS code L8619 to see if that's a covered benefit. Medicare will cover replacement every five years at 80%, and then typically their supplement or secondary might cover that additional 20%, and Part C, or Advantage Plans might have different coverage. As Donna indicated Medicaid is fairly strict about these, and so are many of the private insurers that we see now. They've set policies. They might require the device to be broken or obsolete. The out of pocket costs vary greatly in terms of what patients might have to pay for a sound processor upgrade, but stick with it, work hard, the manufacturers, the clinics will typically help with this, and it's really worthwhile working hard for. So with that I'm gonna pass it back to Donna so she can take you through a couple of cases.

- [Donna] Thank you so much, Terry. The first case that I want to talk about was a specific exclusion for a cochlear implant for a seven-month-old infant in Houston. The child had contracted meningitis, and then became bilaterally deafened. The family did have a Blue Cross/Blue Shield plan, and they saw right away that it had a specific exclusion for cochlear implants. Their request for preauthorization was denied because of that language. The family did research, and determined that there was a state law that was passed in 2017. And this was a rather recent case, actually. And that case required coverage for cochlear implants for policies in Texas, and they did bring this to the attention of the insurer who then approved this particular request for preauthorization, and the insurer changed their policy to cover. So important lesson is you can change it, and insurers sometimes do have different policies for different employers, but you can engage your employer also in this, and you can get it changed. And they successfully did do that, which was great. Another roadblock is a denial. It's really important to understand why you've been denied if that occurs. The one I see

very often is the insurer has equated the cochlear implant with hearing aids, which they don't cover, and someone has read it, and they don't really understand what is being asked. Sometimes a denial is also based on candidacy interpretation, and that's sometimes also possible to address in terms of looking at it. So you want to have the physician write to the insurer. And you can also contact your cochlear implant company, and ask them to help. All three of the companies have staff that work on insurance. One last effort is to appeal to the State Medical Review Board, and we actually have a case study on that one as well. This was a case for a little guy in West Virginia, Zayed, he had had a head injury at 19 months, and experienced single-sided deafness. He had a lot of difficulty hearing in noise, and localizing sound. This was done, actually, prior to the more recent change in the FDA guideline, which now allows coverage for single-sided deafness. The family pursued a cochlear implant under Medicaid. They were denied and had gone through three appeals. They contacted us for help, and we suggested going to Legal Aid in their state, and also then going with Legal Aid to the State Medical Review Board. And the other thing we did was we asked the University of North Carolina to develop a white paper on unilateral hearing loss in children to support their case. They did that and that's up on the website. The family used all those resources, and they sought an appeal through the State Medical Review Board, and they won. It's a great story, and we've written about it on the website. You can go and read about it.

The appeal process will vary by health plan. The plans are required to provide information about how to go about filing an appeal. Some insurers will communicate primarily with the patient, and their family, while others include the physician's office. We find that if there is coordination that generally works the best. Really important to know that denials are oftentimes sensitive. Sometimes it's a very short timeframe, so you have to submit these promptly. And it's really, really important to look at the reason for the denial and clearly address that in the appeal. That process of appeal can be something that you would go to a CI manufacturer for help with. They can give you sample letters to do that, or they can actually contact your insurer if you want. Then

that process typically begins with a written appeal. If that's denied then you have a level two appeal to the plan's medical director, and that may include what's called a peer to peer discussion between the surgeon, and the medical director of the insurance company, or sometimes an independent medical reviewer, which is called a level three appeal. Then there's some options at the state level through government. I mentioned before the State Medical Review Board where the family from West Virginia went, and was successful in getting a change. It's important to determine if your state has legislation that requires coverage. There are a number of states that do have such legislation. The other thing that I neglected to note before many states will cover children with disabilities such as deafness under Medicaid even if the family doesn't normally qualify for Medicaid because of income, so that's another place to look. And you can always request it an in-person meeting to educate and discuss coverage policy. And consider disability evaluation under Social Security, which Terry talked about earlier, and we have information about on the website.

One other place to look is vocational rehabilitation for adults which may cover not the whole surgery, but possibly a sound processor replacement or equipment. Other advocacy that can be pursued is to use social media, and the news media to call attention to a coverage situation, and the need for someone to have a cochlear implant. We're also always happy to help provide ideas on a specific situation, and we do that very often. I'm going to refer you to information that we have on our website for resources. I've just highlighted that with an arrow. That's the homepage of our website, and then we have, actually, a tag called insurance, and on it there's an overview that I did. There's a really nice piece that was done by a parent advocate on processor upgrades, and parts replacement, and getting your cochlear implant company to be considered in network. That's a mom that had two children with cochlear implants, and they both had bilateral, so it was daunting to think about paying out of network for replacements. There's a very nice article that Terry did on disability benefits under Social Security, and there's a captioned video of yours truly talking about insurance and cochlear implants. So that might be something that's helpful for patients as well.

The clinics themselves provide information and support, and there are hospital staff in many cases who are dedicated to obtaining insurance coverage for procedures that they're providing. Most will engage directly with your health insurer. They will submit and track preauthorization, help with appeals, and provide families with guidance. CI manufacturers all have staff to support candidates both people who are seeking a cochlear implant, and existing recipients. Some people can't interact directly with their insurer themselves, and they can do that for you with your permission. They can advise on coverage, and they can work with your insurer so that they become in network, and that's important after the surgery when you're thinking about equipment. They also have information on their websites description of their process, and how they will help bill for equipment. These are some services that are provided by cochlear implant companies. I'm gonna skip through that so we can answer questions.

And some other resources, state organizations for people with disabilities may know about options. I mentioned before the rehabilitation offices being a place to look. State Legal Aid, I mentioned earlier as part of the case in West Virginia. And they have individuals that will help if someone needs that. And some other resources of interest. I mentioned the white paper on single-sided deafness. There's a position paper that we did on pediatric habilitation that can be useful if you're making a case for additional habilitation needed for a child. And then there's materials on the impact of Medicaid on the CI process that will help identify some of the challenges there. And then just other materials on the benefits of CI such as cognitive health. And then the manufacturers all have materials, and we've listed places to look for those. So in conclusion we just would like to remind everyone that insurers typically cover for children and adults. The coverage and out of pocket may vary plan to plan, but by working together recipients, and clinics, and device manufacturers can usually increase the likelihood that coverage will be provided. So that's the end of our prepared remarks. It looks like we have some questions up there. Terry, I think they're all directed at you, so why don't you dive in.

- [Terry] Okay, thank you, Donna. I see one question that states for the FDA labeling are the cutoffs set by the FDA, or by the manufacturers? It's actually the two groups working together after that clinical trial. So a lot of it's set ahead of time at the beginning of the trial, but if they don't meet what they've indicated then the FDA sort of limits what can be said on that. The reason they differ for the different manufacturers is because of different timeframes of when the clinical trials were performed. So if there was a clinical trial today it would be a lot more lenient than the ones that were approved several years ago. It's hard to follow, but it's important for us to follow because we need to know what the insurer's indications are, and if they basically just say needs to meet the FDA then we have to be aware of what those are. I see that somebody also asked who and what sources are the best physicians for implants? And what suggestions because they've never recommended an implant for a family member before. All of the cochlear implant manufacturers on their website have a little tab that says find a clinic, so you can find all the clinics geographically close to you, and start contacting them, and seeking how they'll assist with the insurance preauthorization process, but I would say chances are he's probably covered by insurance for his cochlear implant.

- [Donna] Just to add to that we also have a find a clinic source on our website. It's in the top right side of the homepage. Those are all individual clinics that are active in the American Cochlear Implant Alliance which meets. They're typically more active, and more involved in the process. So we really recommend, also, looking at that resource on our website.

- [Terry] I agree with that completely. So plenty of opportunity for you to find great clinics that will take good care of that family member. There's a question here, great question. Does Medicare cover bilateral implants? I really wish I knew the answer to that. The problem is Medicare has sort of left it up to the discretion of the clinic. I was at a meeting at Medicare several years ago where they were asking professionals to provide information so they could consider stating specifically what their guidelines

would be for bilaterals, and at the end of that meeting they said, Medicare chooses to remain silent on the topic of bilateral implants. So what you'll find is they do mention somewhere about their payment that they will pay for bilateral implants. Some clinics take that as, yes, we can offer bilateral implants. And some clinics take it as, no, we don't offer bilateral implants. Because of the lack of clarity it really varies from clinic to clinic. I'm sorry I can't give you a more straightforward answer than that, but we don't really have one for you. Another question up here is each cochlear implant approved company offers different devices.

Does Medicare restrict the device to over-the-ear, or off-the-ear? So this question is really referring to the sound processor because there's processors that can be worn off the ear, or on the ear. No, Medicare does not specify what kind of sound processor you can have. If someone meets their indications they can receive a cochlear implant, and they can receive any of the FDA approved devices, and they can have their choice of which processor they would like to have. I have another question here about what is off-label cochlear implants? Really going off-label means going outside of the insurance company's indications. It could mean going outside of those published by the FDA, so if your insurance says you have to follow FDA indications, and if you don't meet those, but someone still thinks that you're a good candidate then you're going off the label, but, typically, before you do that you ask permission for payment to do that. So you don't want to do that unless you have the insurance company's permission to do that, or unless the patient is willing to pay cash. If someone pays cash we don't have to follow anyone's indications, but we have to use our best clinical judgment because we don't want to place an implant into someone whose an inappropriate candidate. We're just not limited due to indications due to payment. A lot of it is some people forget that Medicare is an insurance company but it is. They're an insurer and they cover a lot of our patients. So in order to receive payment and coverage for the patient we have to do due diligence and check the benefits, and if they don't meet the indications, and we think they're a good candidate then we ask that insurance if we can go outside of those indications, and if they'll still pay. So that was my answer to

that. I think we have one question. Oh, it just got removed. I think we will wrap up there. I'll join Donna in thanking all of you for listening today. I hope we made a complex topic a little bit more simple for you. Thank you so much for your attention.