Understanding Insurance Coverage of Replacement Processors

Presenters: Allison Feest, Todd Holland

Hello everyone and thank you for making the time to learn more about the changes we are seeing in the insurance landscape related to replacement sound processors and also what considerations that could have in your process and documentation. My name is Allison Fest and I'm a Regional Director at cochlear. I'm joined today by my colleague Todd Holland, who is a Senior manager of Market Access and Payer Strategy and will be presenting shortly.

Many of you have attended a cochlear presentation in the past, and for those who have not, we always start with our mission. Our mission is our true north and the cochlear team keeps the mission in mind by putting the patient at the center of all we do. Our goal is to empower, transform and continue to innovate to bring more implantable hearing technology to those who so desperately need it. Today we're going to be reviewing the transformation that has happened in our replacement sound processor process.

The learning objectives for today's discussion are to review the why behind these changes, learn about the changes that cochlear has already made to our replacement sound processor process, and discuss some considerations for you and your teams related to your process.

Here's a brief agenda of our discussion today. As mentioned, we'll go through our background and process. Todd will walk through our government and commercial payer guidelines. We will discuss documentation and patient support, as well as resources and questions.

So let's get started. Simon Sinek suggests we start with why so so that's where we will begin.

In the next five years, the eligible recipient base is expected to grow exponentially. This is because your teams are doing an amazing job creating access for those who need a cochlear implant or bone conduction device. About 50% of the eligible recipients out there today have a sound processor that is retired. We know these patients are continuing to approach your clinic with a need or want for new

technology. And as cochlear continues to innovate, replacement sound processors are ever more useful and attractive to recipients.

We also know that this process can be very time consuming. Pair that with the changes in the payer landscape creates a challenge of additional time being spent on paperwork for your recipients.

Last fall, eight clinics in my region in the Great Lakes had the opportunity to participate in a pilot related to the replacement sound processor process. The outcomes of those pilot were positive. Our goals were to decrease processing time, for which we did by 24% and also improve the professional's experience make it easier, which was also improved by 43%.

On today's call, Todd will review the different changes we are seeing in Payer policy and requirements and I will discuss how that affects our documentation.

This infographic is a great summary of the changes that have already taken place at cochlear. Regardless if the processor starts with a professional or if the recipient initiates the order by contacting cochlear directly, your process with cochlear will be the same. We are no longer asking for an lmn, a letter of medical Necessity. Instead, we will request the most recent chart note and we will also still ask for your prescription through DocuSign. Once Cochlear receives the Rx and Chart Note, we will submit to insurance, manage the approval, collect any coinsurance, and then you and the recipient will be notified when their processor ships.

On this slide, we have listed the documentation required to initiate a replacement sound processor order at cochlear aob, the order form, the medically necessary reason for the replacement sound processor, the patient's insurance information, and the name of the clinic audiologist and surgeon who support the request for replacement sound processor. Then of course, don't forget that chart notes and prescription are required.

Now I have the privilege to introduce my colleague Todd Holland, who will further walk you through the changes we have observed in the payer landscape. Thank you Allison. Appreciate it. Like Allison said, my name is Todd Holland, one of the senior managers of Payer Access and Payers Market Access and Payer Strategy here at cochlear. So we're going to take a look at government and commercial payer guidelines for replacement sound processors.

It's important to keep in mind the payer policy and medical necessity rationale does not always align with FDA labeling or your clinical decisions. In this next section we will discuss the importance of clinical documentation, how payors think about medical necessity and sound processor replacement criteria.

Clinical documentation is a crucial aspect of healthcare and one of the primary ways that clinicians communicate with each other and to payers. Not only is documentation tied to patient care and safety, there are also regulatory, quality improvement, patient trust, and revenue integrity implications that require accurate documentation in your chart notes. In addition, clinical reimbursement is directly tied to your documentation. In other words, if there is no documentation, there is no reimbursement. I'll pause here to again emphasize the use of replacement sound processor and instead of upgrade.

That shift in language is intentional and fits with how most payers are using those two terms where quote replacement sound processors unquote will normally be the language that is used when payer policies address the criteria that patients and devices must meet for sound processor replacement approvals. And the term upgrade is frequently used in the exclusion section of those policies. You might think of this strategy as a tactic similar to when applying for a job or when you write your resume. You want to pull language from the job description into your resume to align your skills with that job. So we are mirroring the language in pair policy to align with how payers are thinking about replacements versus Exclusions Clinicians must prove medical necessity for payers to approve replacement sound

processors first, let's define medical necessity, and then we will jump into some general payer requirements and what good documentation looks like.

So medical necessity refers to healthcare or supplies that are required to diagnose, treat, or manage a medical condition, illness, injury, or its symptoms. These services must be accepted standards of medical practice and be considered reasonable and necessary for the patient's health. And the services that are primarily for cosmetic or experimental purposes are not going to be considered medically necessary.

So we're now going to take a look at some requirements as to how each one of these payer types covers replacement sound processors.

Before I discuss Medicare's DME policy, it is important to remember that implantable hearing devices like cochlear and auditory osseointegrated implants are normally covered for approved beneficiaries under two separate payer policies. The first policy covers surgery and the implantable hearing system that a candidate will receive, and that policy falls under Medicare's prosthetic policy as a policy that replaces a body part or the function of a body part. The second policy to consider is Medicare's DME policy for durable medical Equipment, and it is in this policy that you will find Medicare's rationale for for when a replacement sound processor might be approved. This is an important distinction in that the prosthetic policy defines the initial system and the DME policy considers replacement sound processors. Our focus here today is DME policy.

So Medicare does have specific requirements for replacement DME and may replace DME under the following circumstances. If the DME is lost or stolen, Medicare may cover a replacement. If the DME is damaged beyond repair, a replacement may be covered. Medicare may cover a replacement DME after that DME has been used for its reasonable useful lifetime, which is generally five years from the date of delivery. Now remember, a prescription from the doctor is required to demonstrate the

continued medical necessity of the replacement item.

So documenting things like the fact that a patient has consistently worn and received benefit from the current sound processor and the expectation that they will continue to receive similar or improved benefit from the replacement sound processor may help to mitigate denials and increase success that Medicare will cover the replacement.

So most commercial plans will publish a policy that outlines their requirements for medical necessity. Typically, you can find these online on the health plan website or provider portal. Examples of medical necessity from commercial plans includes an existing device that is not functional and cannot be repaired a change in the member's condition making the present unit non functional and improvement is expected with a replacement unit. Inadequate response to existing component or components to the point of interfering with the individual's activities of daily living. Some examples of activities of daily living that might impact a patient with hearing loss include a CI recipient who is feeling socially isolated because he has been unable to enjoy a weekly dinner out with family and friends, or a Baja recipient who is struggling to hear her colleagues during meetings.

Both of these examples impact the patient's quality of life and can be used as part of the rationale in your notes as to why a patient might require a replacement sound processor.

So, having just considered medical necessity from a commercial standpoint, we also want to understand commercial policy exclusions. So try to avoid the following in your documentation as justification for a replacement Sound processor pairs will normally consider replacement requests for convenience or aesthetic reasons to not be medically necessary. For example, an upgrade of an existing sound functional sound processor because it has a smaller profile or the patient wants to switch from behind the ear to an off the ear sound processor would not be covered. Also, upgrades of internal or external components of an implantable hearing system solely for the purposes of upgrading

to a system with advanced technology or to a next generation device is normally not going to be considered medically necessary either. Please consult with individual individual payer policies to understand coverage and verify individual patient benefit.

So let's talk about Medicaid for a while and here we're sharing Michigan Medicaid guidelines from 2025 as an example of some of the language that you might see in a Medicaid policy. So Michigan has two statements that address implantable hearing sound processors. They are similar and both call out that for replacement of sound processor the device must be out of warranty and worn for at least four years or the device is irreparable or lost. The policy at the bottom also calls out that for replacement of a sound processor with an upgraded model, documentation must substantiate that the current model is obsolete or a newer generation technology provides additional capacity for continual auditory based improvement. Now, given that each state is different and will have their own policy, we do encourage you to review your state's guidelines to understand sound processor replacement criteria and again to understand the individual patient benefit.

So let's take a look at some of the medically necessary features of Cochlear's current sound processors. So you do have the option to pull information from Cochlear's resources and include relevant information in your prescription for a replacement sound processor. The words that are in bold like 52 DB improvement for N8 or 43% wider frequency bandwidth for BAHA 6 can be used as part of your justification as to why a patient needs a replacement. What this might sound like in Your documentation is SmartSound IQ2 with Scan2 more accurately senses changes in the listening environment and automatically adjusts hearing settings to deliver clearer sound. This can help the recipient in noisy situations where he said he struggles, like in a restaurant or in a meeting.

So in your documentation, by balancing features like smart sound, IQ2, Wiscan 2 with benefits like hearing better in restaurants, that will lead to a better quality of life through activities of daily living and

mirroring pair language by using replacement sound processor instead of upgrade, you will meet the required changes for documentation for sound processor orders. Now I'm going to turn it back to my colleague Allison.

Thanks Todd. Now I'm going to review two key considerations that I hope you will discuss with your clinical team regarding your CI clinic protocol, especially as it relates to patients who need a replacement sound processor. So whether you're a cpn, a relatively new implanting center, or you're a center who's been implanting cochlear implants and bone conduction devices for decades, your patient install base is increasing and you likely feel this in additional time constraints throughout the day. If you're like me, your time is like a toddler, short and precious. And I'm going to walk through some considerations for you and your team to discuss as it relates to the telehealth tools you could utilize in your clinic protocol, especially if that patient needs to re establish care and or the type of information you capture in your chart.

Note how we monitor patient performance has changed over the years and will continue to change as our patient install base increases. The first consideration I'll review is the existing tools for patient monitoring, specifically remote check.

So backing up a bit, let's talk about remote care. Remote care allows you to provide expert care even when the patients aren't with you physically. Remote care encourages the patient to also be at the center of their care, but with you as their expert, right by their side. As a reminder, as far as remote care, cochlear's remote care tools, we have two different technologies. The first is Remote Check and the second is Remote Assist for CI and BAHA assist For baha, Remote Check is used most often.

This allows the audiologist to send a set of tests to the patient to complete on their own time and then the results are then sent back to the audiologist to review at their convenience and really just decide if more intensive follow up is necessary like scheduling a reprogramming appointment. Our second

technology, Remote Assist is the more traditional Live telehealth tool. It allows you to work with the patient remotely and make some changes to the patient's map. Remote Assist is often used when global programming adjustments are indicated following a remote check. So I would ask you to consider how you and your team are using these tools and if you're not, is there an opportunity for one or both to support your replacement sound processor process?

An additional thought for consideration is if you are using one or both, do you have alignment across your clinical team and does everyone know and follow this protocol?

Remote check is a way to monitor performance and outcomes for the majority of patients throughout their lifetime. So here the 8020 rule really applies. It can be used in multiple ways to get a baseline evaluation for routine monitoring or for troubleshooting. For today's discussion I'm going to focus on that baseline eval and monitoring. So to best understand this, I'm just going to talk through a real life scenario.

Let's imagine there's a recipient with an N7 who contacts your clinic for an upgrade and you know that they're asking about a replacement sound processor. The recipient hasn't been seen for a couple of years and reports doing okay, but they read about some of the features in the Innate and believe they would help them at their job in noisy environments. Let's also imagine that your clinic's current process is to see that patient in the clinic to re establish care. But your clinic is currently booking out six weeks for a CI appointment. Something you could consider doing is assigning a remote check to this recipient to get information on performance and status.

From there you can decide what type of appointment they might need to re establish care. Do they need to be seen by an ENT for something medical? Do they need to see you to be reprogrammed? If yes, then they clearly need to be scheduled for a clinic appointment. Or do they need to or do they need to see the RSM to review device use?

You can also get the information you need to re establish care through telehealth.

Assigning a remote check for this patient is a great first Step. But it's only one piece of the information, a moment in time. So what are you going to compare it to? The implant site and the impedances? Yes, you can compare, but you might find value to have an apples to apples comparison for the rest.

This is why we recommend doing a baseline remote check whenever the patient graduates into the maintenance phase of their care plan. Quick recall is that cochlear's care model is looking at the patient journey in three stages after they are implanted. Activate, optimize and maintain. The patient typically graduates to the maintenance phase between three and six months.

So we're going to change this example up a little bit. The patient calls in, wants to upgrade and you assign a remote check. Now let's say you have a remote check baseline as a part of your clinical protocol and this happens between the three and six month point when the patient enters the maintenance phase. Now you have a comparable for their performance. So you have a baseline that you can compare a diagnostic remote check, this being, this diagnostic being, anything after that first is considered a diagnostic after the baseline.

As a reminder, when you assign remote check, the patient will be notified to complete it in their app. Once they complete the check, the audiologist gets notified in the portal or via email if the notifications are enabled and from there you review it and compare the results to the baseline to see if there have been any changes. So for simplicity's sake, you can think of it as a screening tool to decide if the patient is still doing well and making the progress that you would expect, or if there are any red flags that require further follow up and reprogramming.

The next consideration for using telehealth for data collection is considering when and how you use remote check in place of appointments. Many of the clinics across the US are already assigning a baseline at or shortly after that three month check and then using remote check in place of the six month if there's not a need for reprogramming. So I may be preaching to the choir, but if you haven't yet adopted remote check, this is one option to save you and the patient some precious time. To make the logistics a bit easier to conceptualize, some clinics are assigning both the baseline and the follow up diagnostic when the patient is seen for their three month appointment. It's nice because you can review the action for the patient, what they're going to do and complete the baseline, and some clinics even do it while the patient is in the clinic with them and then just let the patient know their next appointment is a telehealth appointment at the six month mark.

@ that point whenever the patient completes the remote check, then you can decide if they need to be seen for a six month appointment or if they're progressing as expected.

I realize this is a very quick review of remote check as well as the care model, so if anyone would appreciate a review please let your cochlear rep know because we are here to help.

This is information on what is required by Cochlear whenever we are looking at a replacement sound processor. So the first seven items are required to initiate the order. And just know that cochlear will request that chart note and prescription from the clinic whenever we received the rest of this documentation we've discussed the why is due to the changes in payer policy. Remote check is one how to collect the information on a recipient who's interested in that replacement sound processor and now we'll discuss a bit about the what information could you consider collecting? Something that Todd had mentioned and an additional item worth reviewing is to consider activities of daily living or ADL's in your chart notes from the beginning so you have a comparable when the patient is interested in that replacement sound processor years down the road.

ADL's are something used in many medical professions, however not always in audiology and they are, as Todd mentioned called out in multiple payer policies and as such something to consider documenting. A few examples of ADLs are here safety and quality of life. An example of this may be hearing while operating a vehicle or hearing announcements in a public place, social or entertainment. And Todd had an example of this is engaging on a video call like we are today or communicating with those loved ones in a noisy environment or in the workplace or school. So understanding verbal instructions or being able to provide feedback in a noisy environment.

Think about how you are using think about how you are measuring these with your patients and are ADL's included in your clinic protocol. Consider Consider utilizing a remote check baseline and comparing it to a diagnostic remote check later as a way to document your patient's ADL performance.

Cochlear is a manufacturer and we will not and should not prescribe clinical decision. We are here however to help you understand the options, help you understand what's going on in the payer landscape and just present ideas for consideration. So some additional considerations for monitoring visits are listed here. You can think about what are the patient's ADL's and how are they being met? What is the processor obsolescence, processor status and patient performance and how would a new sound processor better support the patient's performance, especially related to their ADL's.

There are also a few do's and don'ts as a best practice for your documentation. So the do's here are consider including ADL's and how a replacement provides processor will benefit the patient to better achieve those ADL's. Know and keep in mind that your chart notes will likely be called upon if and when this patient needs a replacement sound processor now and moving forward in your chart notes, use replacement sound processor rather than upgrade. And know that we have teammates at Cochlear whose entire job is to help make this process easier for you and your patients. So consider adding the RSM to your clinic protocol.

Some don'ts don't send chart notes in that are over two years old. Remember to focus on the benefit to the patient rather than a technology advancement in your notes. And remember that upgrade is a no no word in a chart note.

There are multiple resources available when looking at your process. If you're interested in more information, be sure to reach out to your cochlear rep. We will also include a few case examples to get you started about the new process.

So this first case example is a sound processor that is beyond its useful life. So this gentleman is 65 years old. He called the clinic, he's having some problems with his processor. They sent him a remote check and on the questionnaire he reported trouble hearing and background noise. And then they assigned a remote assist visit and he reported problems specifically in restaurants and hearing his family on the phone.

So that's our case history here.

And then what are we looking at for this specific example? And this is what we would be considering in the chart note the patient reports difficulty having phone conversations and sees direct streaming to a CI as a means to overcome the challenge. The patient is currently using the device on a limited basis due to financial constraints which limit his ability to purchase disposable batteries to power the device. His current N6 sound processor is out of warranty, over 5 years old and has reached the end of useful life. We discussed sound processor replacement sound we discussed the replacement of his N6 sound processor with an N8 from Cochlear, the sole provider of this device and that is compatible with his internal this is medically necessary for reliable access to sound for daily communication and safety.

And he selected the N8 sound processor in black with a TV streamer. So getting into some of those details, this audiologist has then went through what the patient recommendations would be is to follow

up in three months and obviously continue that oral rehab. And to continue if we have eyes open, ears on.

Thank you for making the time to walk through the changes that we are seeing in the payer landscape. Different considerations that you and your team can discuss and I hope this was helpful. Make it a great day, everybody.