A step-by-step guide to the reimbursement process
This guide is intended to help you:

• Access the best and most advanced implantable hearing solutions for your patients.

• Maximize your payer outcomes.
When dealing with any health plan, there are eight critical components that contribute to the success of securing coverage and appropriate payment for any surgical treatment or technology.

This reference manual describes how to manage each one:

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Cochlear™ Baha® BP100
Bone Conduction System
HEALTH PLAN – DID YOU KNOW?

- Your health plan policy is a contract between you and the insurance company.
- This contract details the specifics of what is covered and what is not covered under your health plan.
- Your health plan is required by law to abide by the terms of this policy.
- Most health plan policies have a glossary within the physical contract, which is very useful for definitions of important terms used in the contract or by your health plan.

WHAT ARE YOUR RIGHTS?

- Your health plan must provide subscribers and their dependents a reconsideration or dispute process for any unfavorable decisions.
- Your health plan must provide access to the health plan policy (benefit handbook).
- Your health plan must provide you with in-network physicians and facilities to ensure you are given the highest benefit available for covered services.

HOW YOUR HEALTH PLAN SHOULD WORK FOR YOU...

- Your doctor recommends an auditory prosthetic device for your hearing impairment.
- You or your doctor submit a written request to obtain and verify pre-determination of benefits and/or pre-certification of medical necessity based
on your health plan policy and the health plan’s medical policies for the recommended procedure and device.

- Your health plan notifies you and your doctor in writing if the procedure and device is covered or is not covered.

- You and your doctor move forward with the services if your health plan approves the request, less any co-pay, co-insurance, or deductible.

UNDERSTAND YOUR HEALTH PLAN COVERAGE

- Review documentation provided to you by your health plan. (i.e. request a copy of your benefit handbook).

- Find out which services are covered and which are not.

- Be aware of the processes involved in requesting and obtaining coverage.

You should contact your health plan to determine coverage as well as your estimated out-of-pocket expenses, prior to surgery. Services include:

- Auditory prosthetic device components.
- Hospital surgical fees.
- Physician fees.
- Surgical fees.
- Anesthesia.

QUESTIONS YOU SHOULD ASK YOUR HEALTH PLAN:

- Am I covered for surgery for implantation of the auditory prosthetic device?
- Am I covered for the auditory prosthetic device?
What is my benefit for the surgery and device?

Do I need pre-authorization?

What is my benefit maximum dollar amount?

Have I met my deductible, catastrophic, or lifetime maximum?

Is my physician and/or hospital in or out-of-network?

How long does the pre-determination or pre-authorization process typically take?

Play an important role in obtaining payment by writing to the medical director of your health plan. Explain your medical diagnosis relative to auditory prosthetic device and why you and your physician are confident that the auditory prosthetic device is the best treatment option for you.

In the event that your request is denied, find out the reason behind the denial and address this specific concern in writing. Your health plan will have an established appeal or disputed decision process for you to follow. Be sure to:

- Specifically address the reasons for the denial stated in the correspondence from the health plan. Provide additional information regarding your medical history and your necessity for the auditory prosthetic device.

- Discuss the denial with the medical director or other contact indicated on the denial letter from the health plan.

- Contact your human resources representative or union representative to discuss your denial issue. They may contact the health plan on your behalf.
Predetermination

Predetermination is a process established by Health Plans which allows your physician to submit a treatment plan to your Health Plan prior to surgery. The Health Plan reviews the treatment plan, your insurance benefit plan and Medical Policy to determine if

- The treatment is covered.
- If you are a covered member.
- The amount of co-payments/co-insurance, deductibles.
- Your plan’s maximum benefits.

It is strongly recommended that Pre-Determination of benefits for the implant system is performed on all candidates, except for Medicare beneficiaries. Your provider will assist you with this process.
Medical Necessity

All Health Plans will restrict coverage to only include services they consider “Medically Necessary”. Additionally, health Plans have their own definitions of what is “Medically Necessary” and/or “Experimental or Investigational”. These definitions are typically tied to a documented Medical Policy based on their own technology assessment criteria or an independent Technology Assessment review. During the predetermination process, your physician’s office will contact the health plan and request a copy of your health plan’s policy on medical necessity.

If your Health Plan does not consider coverage of the FDA approved device, it is recommended that you work through your physician’s office and the predetermination process or submit a letter of medical necessity and comprehensive supportive material (see steps involved in the predetermination and preauthorization process) to educate the provider on the scientific evidence supporting use of the technology and its applicability to the patient’s treatment plan. Cochlear™ additionally provides support through their OMS. This service is available to advocate and support the insurance process.
Coverage
determinations may vary in specific instances based on the following:

- The terms of the applicable coverage plan document in effect on the date of service.
- Applicable laws/regulations.
- Relevant peer-reviewed published collateral source materials including Coverage Policies.
- The specific facts of the particular situation.

Additionally, if the terms of the Health Plan’s coverage policies are inconsistent from the terms of your specific benefit coverage plan, the terms of your specific coverage plan will always override the Health Plan’s Medical Coverage policies.

REIMBURSEMENT AND BILATERAL COCHLEAR IMPLANTATION

You and your surgeon may select from two options when considering bilateral cochlear implantation:

- Simultaneous implantation – both ears implanted during the same surgical session.
- Sequential implantation – CI implantation in each ear during separate implantation surgical sessions (can range from weeks to years).
Depending on which option you select, the following factors should be considered:

Commercial Health Plan Coverage

- Does your health plan cover simultaneous cochlear implantation?
- Review your health plan’s “certificate of coverage” provided by your health plan to determine benefit coverage.
- Make sure that the health plan will cover the surgery, cochlear implant (CI) devices, and post-surgical rehabilitation.
- Check to see if prior authorizations for both the surgery and CIs are required.
- Read the health plan’s cochlear implantation medical policy to determine if the health plan considers bilateral cochlear implantation “medically necessary” and in what situations (simultaneous and/or sequential).
- If a cochlear implantation medical policy does not address bilateral implantation, have your surgeon’s office compile a predetermination packet to send to the your health plan to determine coverage.
- Beware of potential financial responsibilities with either option (i.e., deductibles, co-payments, coinsurance).
- Some of the larger commercial health plans cover bilateral cochlear implantation; however it is important to clearly understand the coverage and payment parameters.
- Even though the health plan may have a general coverage position on bilateral cochlear implantation, it does not mean that your health plan has the same coverage.
• Please note that coverage does not guarantee payment.

• For simultaneous bilateral cochlear implantation, many health plans will reimburse outpatient surgical procedures utilizing the Medicare payment methodology (150% of charges, i.e. Medicare pays for the second surgery at 50%).

• If your health plan denies coverage for bilateral cochlear implantation, the surgeon and/or the patient have a right to appeal the health plan’s coverage decision.

☐ Health plan should provide you and your surgeon information on appeal rights.

☐ You should work with your surgeon to assist in the appeal process.

☐ Your surgeon should prepare a letter of “medical necessity” outlining the patient’s need and value for bilateral implantation, copies and results of medical tests, published peer-reviewed literature supporting bilateral implantation, and detailed patient history applicable to the request.

MEDICARE

• The current Medicare coverage policy does not clearly delineate whether bilateral cochlear implantation is covered for either simultaneous or sequential surgeries. Contact the Medicare Administrator Contractors (MACs)/Intermediaries/Carriers to request a medical coverage policy determination for bilateral coverage.

• Individuals who have previously been implanted through their commercial health plan and are now covered by Medicare
may be covered for the second cochlear implant through Medicare. However, it is important for your surgeon's office to check with the applicable Medicare MACs/Intermediaries/Carriers to request a medical coverage policy determination prior to providing the service.

• Traditional Medicare does not offer an option for predetermination or prior authorization of coverage. Therefore, the only option is to request a policy interpretation.
• Interpretation may vary by MAC and/or Intermediary/Carrier.
• Medicare reimbursement will vary depending whether the bilateral cochlear implants are simultaneous or sequential.

MEDICARE ADVANTAGE PLANS
• Medicare Advantage Plans must offer the same benefits defined by traditional Medicare but often cover additional services.
• Since the traditional Medicare coverage policy does not clearly delineate whether bilateral cochlear implantation is covered, it is best to work with your surgeon's office in contacting your Medicare Advantage Plan and inquiring about benefit and coverage determinations.
• Medicare Advantage Plans may have policies for predetermination of benefits, preauthorization requirements, and appeal processes. Work with your surgeon's office to check with the Medicare Advantage Plan to explore the options available.
MEDICAID

• Coverage for bilateral cochlear implantation is very inconsistent.
• Work with your surgeon’s office to check on state Medicaid plan or Medicaid HMO to determine coverage and benefits.
• State Medicaid plans and Medicaid HMOs have processes to appeal claims on an individual basis based on medical necessity.
• Prior authorizations of bilateral implantations are generally required.
Upgrades and Replacements

Upgrades/replacements to the Cochlear™ external product category

Cochlear provides the following information as guidance to assist with your sound processor replacement insurance coverage questions. Medicare, Medicaid, Medicare Advantage, and commercial health plans all have guidelines for when they might cover a replacement or upgrade for sound processor (or other parts and accessories).

COMMERCIAL HEALTH INSURANCE AND UPGRADE COVERAGE.

Each health plan (a.k.a. insurance plan) is different and has its own criteria. It is important to check your plan regarding coverage criteria on replacement parts and upgrades. Typically, health plans cover replacement sound processors based upon the following two requirements:

- Before and after audiologic test results or information and data clearly predicting improved performance with use of the new technology (i.e., medical necessity).
- If the current processor has been continuously used for 5 years, replacement with improved technology may be possible.
Your clinic may assist in the process by:

- Testing your performance with your current processor and comparing it to the performance results with the upgraded sound processor.
- Predicting improved performance based on the group average clinical data available.

Medical Necessity

To request coverage and payment for medically necessary services, a letter of medical necessity (LMN) must be written by your current medical professional treating your medical condition and situation. Cochlear Americas cannot establish medical necessity and consequently, does not supply sample LMNs.

MEDICARE AND UPGRADE COVERAGE

Medicare classifies Cochlear’s sound processors and associated parts and accessories as prosthetics. As such, all of Cochlear’s parts and accessories are subject to the durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS") requirements under Medicare.

Medicare’s Claim Processing Manual, provides that Medicare will cover replacement of DME equipment under the following circumstances:

- Loss.
- Irreparable damage.
- Irreparable wear.
- Where required because of a change in the patient’s condition.
DOES STATE MEDICAID COVER UPGRADE SOUND PROCESSORS?

Coverage for upgrade sound processors is subject to each state’s Medicaid Plan guidelines, although Medicare’s guidelines generally provide a good starting point for Medicaid. A good approach is to have your doctor’s office submit a preauthorization request, utilizing Medicare’s guidelines and include a letter of medical necessity or current physician’s order documenting the basis for recommending the upgrade processor to determine coverage.
Preauthorization/Pre-Certification

Although pre-determination is an optional process offered by many health plans, the pre-authorization/pre-certification is mandatory for most health plans.

What is the difference between Pre-certification and Pre-authorization?

- Pre-certification confirms eligibility and collects information prior to inpatient admissions and selected ambulatory procedures and services.

  It is comprised of two components:
  
  - Notification – the process of documenting a coverage request.
  
  - Coverage Determination - review of plan documents and submitted clinical information to determine whether the health plan’s clinical guidelines and criteria for coverage are met.
  
  - The pre-certification process.
  
  - Encourages communication your doctor and/or yourself in advance of the procedure, service or supply.
  
  - Enables the health plan to proactively identify patients who may require continued disease management.

- Pre-authorization is the process used to confirm whether a proposed service or procedure is:
  
  - Medically necessary.
  
  - Covered for the proposed care.
• Covered for the proposed length of stay (if applicable).
• Scheduled for concurrent review.

☐ Pre-determination is an optional process offered by many plans, the pre-authorization and/or pre-certification process is mandatory for most plans.

Most health plans require providers to:

☐ Seek advanced approval for all elective inpatient medical and surgical admissions, and most outpatient surgeries.
☐ Obtain approval within a specific timeframe.
☐ Verify coverage and benefits of the proposed patient’s treatment plan.
☐ Provide applicable coding and medical necessity for services/procedures requested.
Managing Denials

The reasons your health plan may deny your proposed treatment...

- The requested procedure is specifically listed as non-covered under the terms of your health plan policy.
- The procedure may be covered, but only under certain circumstances: (i.e. You must utilize a physician that is in your health plan’s network).
- Your physician is requesting a procedure using technology, which your health plan considers as an experimental or investigational procedure.
- Your health plan determined the procedure being requested is not medically necessary based on the diagnosis and medical documentation that was submitted.
- Your health plan misunderstands the technology and denies the implant stating it is a hearing aid.

Appealing Denials from your Health Plan

If you receive a written denial letter from your health plan, define the reason your request was denied.

These are some of the common reasons given for denial of coverage.

- The documentation provided did not justify medical necessity to the health plan base on the established medical policy utilized in the review.
- The procedure requested was determined to be benefit exclusion.
**BENEFITS VS. MEDICAL NECESSITY**

**Health Policy Benefit** - is a service, test, procedure or treatment that your health plan has agreed to cover as long as the medical necessity has been approved. You should understand that your Health Policy Benefit always supersedes approval for Medical Necessity. As an example if your request was approved for Medical Necessity, the claim may still be denied as a Health Policy Benefit exclusion.

**Medical Necessity** - is a review by your health plan that determines if a requested service, test, procedure, or treatment is:

- In accordance with generally accepted standards of medical practice.
- Clinically appropriate in terms of type, frequency, extent, site and duration.
- Not primarily for the economic benefit of the health plan and purchasers or for the convenience of the patient, treating physician or other healthcare provider.

If your health plan determines that the request does not meet the health plan’s definition of “Medical Necessity” or is not appropriate the request may be denied.

**HEALTH PLAN APPEALS PROCESS**

Although the appeals process will vary by health plan, your health plan should offer a step by step process that allows members the opportunity to dispute denial for service. This process will be available to review in your benefits handbook or by contacting the customer service department by phone at the number listed on the back of your insurance card. In general most carriers follow the steps listed below.
Level 1- First level appeals are usually reviewed by your health plan’s appeals department. The Medical Director who was involved in the denial may be involved also.

Level 2- Second level appeals are reviewed by Medical Directors and Appeal department staff that were not involved in the original decision for denial.

Level 3- The third level appeals are usually completed by an independent (outside of the health plan) reviewer who enlists the assistance of a physician who is board certified in the same specialty as the requesting physician. If an appeal is submitted at this level there can be charges to the patient for this service.

**KNOWING WHEN TO APPEAL OR NOT TO APPEAL**

If the denial reason states that the health plan needs more information for the review, you may only need to gather that information and furnish it to the appropriate party who has requested it. Your physician may be able to assist you with this.

**You should consider appealing if:**

- The procedure that was requested is different from the service that was requested or the health plan defines the requested procedure differently than your physician has defined it.

- The request was denied for medical necessity and your physician has reviewed the medical policy and he feels the criteria have been met.
You should consider not appealing if:

- Your maximum benefit has been met.
- Your policy specifically excludes coverage of the exact procedure that your physician has requested (by name or function).

**DEVELOPING A WRITTEN REQUEST FOR APPEAL OR GRIEVANCE.**

Gather information from as many sources as you can. Some of the resources that may guide you are:

- Your benefits handbook from the health plan. This document should identify:
  
  - Timely filing requirements for appeal submissions.
  
  - The name of the department or contact person and
  
  - List an address or possibly a fax # that the appeal should be submitted to.

If you do not understand the information in this handbook contact the customer service # on the back of your insurance card for additional assistance.

- Communicating with your treating physician or the physician’s staff. They may be able to:
  
  - To contact the health plan and assist in the appeal process or
  
  - Supply you with additional clinical information supporting this request

If the written denial states that a peer to peer review is available, be sure to give your physician this information as soon as possible.
Verify through your employer whether you are being covered by a “Self Funded” or “Fully Insured” policy.

- Fully insured policy - “an employer purchases insurance coverage from a licensed health plan and that company assumes all management of benefits and financial risks”.

- Self funded policy - “an employer who underwrites the financial risk and has the final determination of coverage decisions”.

Identifying which coverage you have is very important if the health plan who denied your request may not have the final decision. It may be possible to discuss this denial with your Human Resources department to seek a more favorable decision.
From patient to health plan medical director
Date
Medical Director Or Appropriate Department
Health Plan
Address
City, State Zip Code

RE: Request for coverage decision for (INSERT patient name, policy #, date of birth, and group #).

I am writing to appeal (INSERT name of health plan)'s recent denial of coverage for (INSERT name of auditory prosthetic) to restore my hearing. This denial was issued because (INSERT denial reason as stated in letter from health plan).

This denial is inaccurate because (INSERT information explaining why the denial reason is not accurate. Refer to Appeal Explanations provided).

I have been diagnosed with (INSERT diagnosis). My physician, (INSERT name), advised me that clinical evaluation verifies that I am a qualified candidate for this treatment option which stands alone as the only treatment for my type and degree of hearing loss.

As stated above, (INSERT physician's name) has diagnosed me with (INSERT diagnosis). (INSERT brief description of how this hearing loss affects your daily life - social situations, work, etc.)
I understand that in order to receive this auditory prosthetic system, coverage will be required for the following charges: the Auditory Prosthetic components, hospital surgical fee, physician surgical fee, and anesthesia.

I look forward to your response. Please do not hesitate to contact me or (INSERT physician's name) if additional information is needed.

Sincerely,

(INSERT patient’s name)

(INSERT patient’s complete address)
Options to Consider When Insurance Denies Benefits for Auditory Prosthetics

If all options for receiving coverage through your health plan have been exhausted, below are further options that you may wish to consider.

☐ Explore your option of switching insurance plans when enrollment periods begin.

☐ Contact the State Vocational Rehabilitation office to see if they can offer assistance with the costs.

☐ Contact local service organizations, such as Lions Club or Sertoma Club to ask if they will sponsor fundraisers.

☐ Contact the Colorado Neurologic Institute (CNI). This is an organization that assists candidates with no other means receive the device. The website is www.thecni.org.

☐ If the candidate is a child, check to see if there are any special State programs that offer assistance to children with disabilities or check to see if they qualify for State Medicaid benefits.

Another option available is OMS Cochlear Americas. OMS provides prospective recipients with insurance preauthorization and verification support at no charge for Auditory Prosthetics. Contact OMS for assistance in verifying that procedures are covered by insurance, for assistance in securing preauthorization for procedures and /or for assistance in challenging insurance denials.
The information provided in this document is provided as guidelines only to address the unique nature of implantable hearing solutions technology and is not intended as legal advice. There is no guarantee that following these guidelines will result in any form of coverage or reimbursement from any insurance company or federal health care program payer. The information presented herein is subject to change at any time. This information cannot and does not contemplate all situations that a health care professional may encounter. To be sure that you have the most current and applicable information available for your unique circumstances, please consult your own experts and seek your own legal advice regarding your reimbursement needs and the proper implementation of these guidelines.
This is Cochlear’s promise to you. As the global leader in hearing solutions, Cochlear is dedicated to bringing the gift of sound to people all over the world. With our hearing solutions, Cochlear has reconnected over 180,000 cochlear implant and Baha® recipients to their families, friends and communities in more than 100 countries.

Along with the industry's largest investment in research and development, we continue to partner with leading international researchers and hearing professionals, ensuring that we are at the forefront in the science of hearing.

For the person with hearing loss receiving any one of Cochlear’s hearing solutions, our commitment is that for the rest of your life you will Hear now. And always

For further information please contact your local Cochlear representative or visit us on the web at: www.cochlear.com

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5. Multi-center validation of the Nucleus 5 Sound Processor. Preliminary speech perception data from initial fit (N=39.)

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