



Cochlear[®]
Hear now. And always



Pediatric candidacy, evaluation and fitting protocol

Cochlear[™] bone conduction
hearing systems

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Cochlear bone conduction portfolio



Selecting the most appropriate hearing technology is critical to a child's hearing success. Early access to sound is proven to make a difference in helping children learn, engage and fully experience the richness of their environment.¹


Cochlear is proud to offer a wide portfolio of surgical and non-surgical systems that can be used to treat children with hearing loss through bone conduction.

This guide will walk you through the treatment determination and care pathway including:

- Candidacy identification
- Demonstration and evaluation of bone conduction solutions
- Bone conduction treatment determination
- Patient fitting and monitoring
- Next steps on the child's hearing journey
- Billing


* Remote Assist for Baha for compatible Baha sound processors is intended for a follow-up adjustment or setup of a replacement or upgrade sound processor for suitable qualified patients based on clinical judgment. Only available at clinics that have enrolled in Remote Care. For compatibility information visit www.cochlear.com/compatibility.

^ In the United States and Canada, the Osia System is indicated for children ages five and older, the placement of a bone-anchored implant is contraindicated in children below the age of 5.


Osia® System


Active BC implant system
Piezoelectric technology
Powered for performance— excels in the high frequencies ²
Easier MRI access at 1.5 T and 3.0 T with magnet in place ³
For all patients, from children to senior adults, who want the latest technology [^]
Up to 55 dB HL bone conduction thresholds




Baha® Start

Non-surgical BC system
Electromagnetic technology
Faster access to sound with Cochlear Lend an Ear Program
Access to care when and where patients need it with Remote Assist for Baha*
For infants and children, patients not ready for a surgical solution, and bone conduction demonstration
Up to 55 dB HL bone conduction thresholds




Baha® System

Percutaneous BC implant system
Electromagnetic technology
LowPro™ or extended 2 mm snap coupling
Access to care when and where patients need it with Remote Assist for Baha*
For patients with factors that preclude an Osia 2 System
Up to 55 dB HL bone conduction thresholds



Candidacy identification

Goals

- Identification of hearing loss (Conductive or Mixed Hearing Loss, Single Sided Deafness)
- Establish a baseline for continued monitoring of hearing outcomes



Audiological evaluation

- Case history
- Otoscope examination of the ear and ear canal
- Tympanometry for both ears
- Acoustic reflex measures (optional)
- Otoacoustic emissions (optional)
- Questionnaires (hearing, communication, quality of life)

Depending on the age and/or developmental capabilities of the child:

- Ear- and frequency-specific bone conduction hearing thresholds.⁴ Include air conduction when anatomically feasible.
 - Auditory Brainstem Response (ABR) with bone conduction transducer
 - Behavioral audiometry
- Speech audiometry (threshold and suprathreshold)



Medical examination

- Medical evaluation to determine etiology and medical treatment (if needed)



Conductive or mixed hearing loss indications

Ear to be implanted

Bone conduction Pure Tone Average (PTA) (500, 1000, 2000, 3000 Hz)

≤ 55 dB

Air conduction thresholds are not considered

Age[^]

Implantable solutions:
Osia: age 5 years and older (US and Canada)

Baha: age 5 years and older (US and Canada)

Non-surgical solutions:
any age

Additional considerations

ABG ≥ 30 dB

Patients with an air-bone gap (ABG) of more than 30 dB PTA will experience significant advantages from a bone conduction system as compared to using an air conduction hearing aid.⁴

When to choose bilateral

Bone Conduction PTA:
Difference between ears in bone conduction PTA is within 10 dB

At individual frequencies:
Difference between ears in bone conduction thresholds at individual frequencies are within 15 dB



Single-sided deafness indications

Poor ear

Profound sensorineural hearing loss

≥ 80 dB

Good ear

Air Conduction PTA (500, 1000, 2000, 3000 Hz)

≤ 20 dB

Age[^]

Implantable solutions:
Osia: age 5 years and older (US and Canada)

Baha: age 5 years and older (US and Canada)

Non-surgical solutions:
any age

Additional considerations

Patients who cannot or will not use an air conduction CROS hearing aid

Patients with contraindications for cochlear implantation

[^] In the United States and Canada, the Osia System is indicated for children ages five and older, the placement of a bone-anchored implant is contraindicated in children below the age of 5.

Bone conduction demonstration and evaluation



Goals

- Demo the bone conduction system
- Complete the bone conduction evaluation
- Provide recommendations based on evaluation results and other considerations
- Create audiological treatment plan in conjunction with medical treatment plan to address hearing needs of the child



Demonstration and Evaluation with a Baha® 6 Max Sound Processor

- Program the Baha 6 Max sound processor using the child's audiometric information
 - Use BC Direct Thresholds, if possible. If not available, use audiometric or ABR bone conduction thresholds
 - At least one low- and one high-frequency bone conduction threshold is necessary for the affected ear(s) to be fitted⁵
- Snap the processor to the Softband or SoundArc and place on child's head
- Conduct an aided bone conduction evaluation[^] in the soundfield using the custom program
 - Isolate the test ear through plugging, muffing, or masking the non-test ear as appropriate for the child and indication
 - Determine aided benefits using frequency-specific and/or speech stimuli

[^] Clinical studies have shown that a non-surgical bone conduction solution, like Baha Start, is an effective method for predicting outcomes before bone conduction implantation.^{6,7}

Equipment

- Baha® 6 Max Sound Processor
- Softband and/or SoundArc™
- Cochlear™ Baha Fitting Software installed on fitting computer along with NOAHlink® Wireless Programming Interface
- Audiometric test equipment with soundfield capability
- Reinforcers and toys used for Visual Reinforcement Audiometry (VRA) testing and Conditioned Play Audiometry (CPA)
- Recorded speech testing material



Baha Softband



Baha SoundArc

Aided soundfield testing of ear to be implanted

Depending on the age and/or developmental capabilities of the child:

- Behavioral audiometry to measure thresholds from 500 Hz through 6000 Hz using narrow band noise stimuli
- Consider measuring aided thresholds with the Ling 6(HL) test (v2.0)⁸ with calibrated, pre-recorded Ling 6 sounds
- Speech audiometry (threshold and suprathreshold)

Tip

The Ling-6(HL) test developed at Western University⁸ contains calibrated recordings of the Ling 6 sounds. Each of the Ling sounds is presented to measure detection and plotted on an audiogram. Since the stimuli are phonemes of speech, they may be more clinically relevant and would be less likely to interact with automatic features of the signal processing enabled in the sound processor.



Bone conduction treatment determination

Goals

- Determine the treatment pathway for the child, including the appropriate bone conduction solution



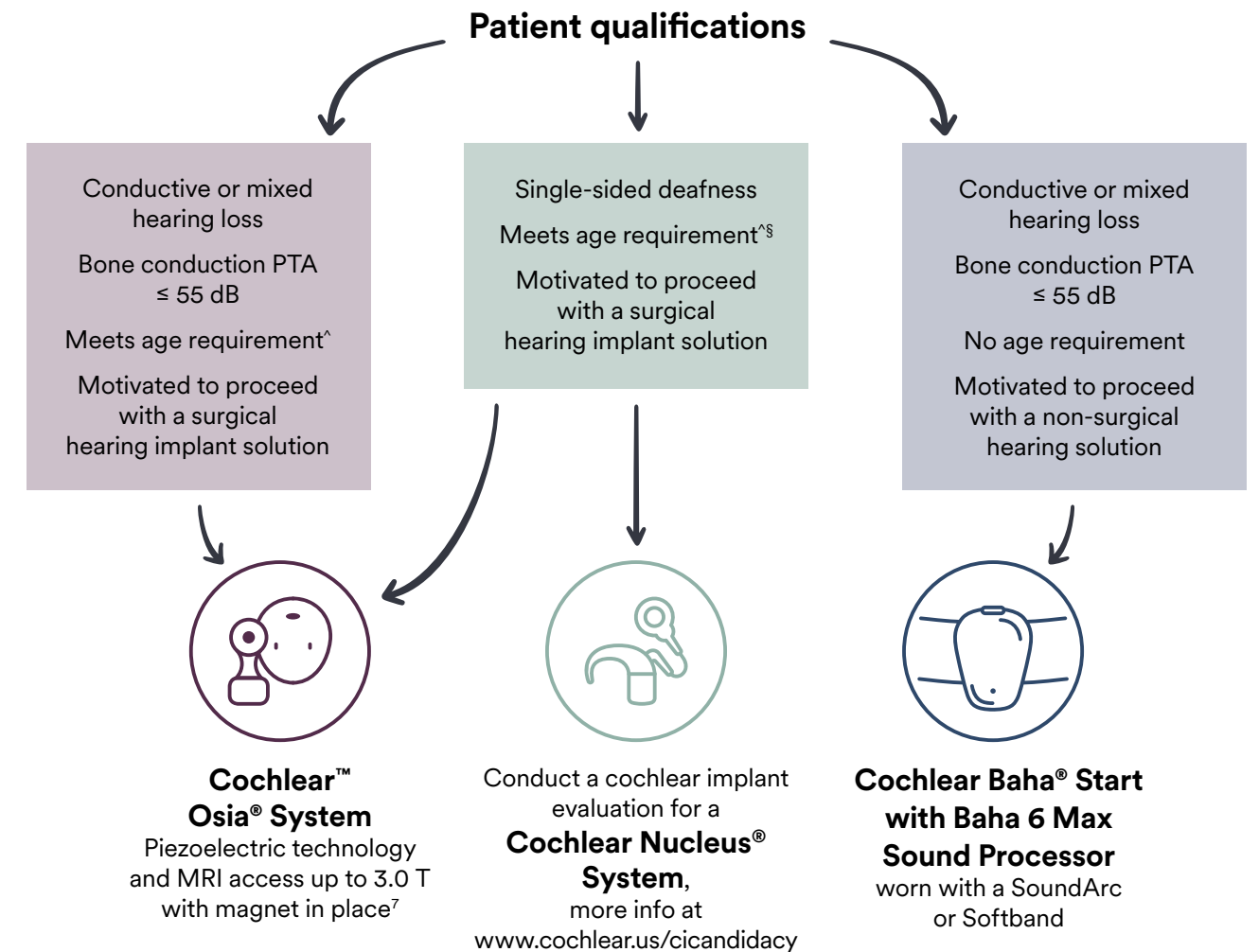
Determine treatment

A multi-disciplinary team can provide families with a holistic care plan for the child and the information needed to make decisions regarding treatment options. The team may consist of the parents, surgeon, audiologist, speech-language pathologist, social worker, and early interventionist.

Take into consideration

- Bone conduction evaluation results
- Medical evaluation and surgical plan
- Patient use duration of bone conduction device (short term vs. long term vs. intermittent)
- Surgical or non-surgical solution
- Unilateral or bilateral fitting
- Concomitant disorders
- Daily use and maintenance of a bone conduction device
- Patient health plan benefits and coverage

Bone conduction solution recommendations

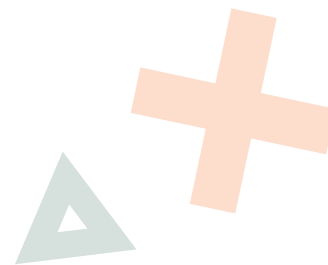


Additional recommendations for specific cases

Patient with factors that preclude an Osia 2 System	Consider the Cochlear Baha Connect System[^] with Baha 6 Max Sound Processor
Baha Solution patient requiring additional clearance between their skin and the sound processor	Consider the Baha 6 Max Sound Processor with the 2mm Extended snap coupling , instead of the LowPro™ snap coupling
Patient with bone conduction PTA threshold > 55 dB	Conduct a cochlear implant evaluation for a Cochlear Nucleus System , more info at www.cochlear.us/cicandidacy

[^] In the United States and Canada, the Osia System is indicated for children ages five and older, the placement of a bone-anchored implant is contraindicated in children below the age of 5.

[§] In the United States and Canada, the Nucleus System is approved for children with single sided deafness ages five and older. For more information on general Nucleus candidacy criteria, please visit <https://www.cochlear.com/us/en/home/diagnosis-and-treatment/how-cochlear-solutions-work>.





Bone conduction counseling considerations

- Counsel on the optimal option for the patient
- Discuss wireless accessories, apps and connectivity options and how these may be an effective complement to a bone conduction solution
- Discuss retention options
- Discuss appropriate expectations
- Discuss MRI considerations
- Discuss cost, reimbursement and funding
- Osia patients:** Counsel on the expected improvement in sound quality with Osia, compared to a demonstration with non-surgical solution⁹
- SSD patients:** Counsel that hearing in the profound ear will not be restored but the bone conduction sound processor will send sound from the profound side to the better hearing ear
- Baha 6 Max Sound Processor patients:** Discuss Remote Care via Remote Assist* to supplement in-clinic care



Surgical counseling considerations

- Bone conduction implants are typically a same day, outpatient procedure
- The procedure generally takes about an hour, with additional time in the preparation and recovery areas
- Patients typically go home the same day
- Most patients are back to their normal routine after a few days for recovery



Next steps

- Review Cochlear Bone Conduction Solutions: Your guide to preparing for surgery (BUN535)
- Provide Engagement Manager contact information to the family
- Complete order form

*Remote Assist for Baha for compatible Baha sound processors is intended for a follow-up adjustment or setup of a replacement or upgrade sound processor for suitable qualified patients based on clinical judgment. Only available at clinics that have enrolled in Remote Care. For compatibility information visit www.cochlear.com/compatibility.
The Cochlear Osia 2 and 2(l) Sound Processors with Aqua+ are dust and water resistant to the level of IP68 of the International Standard IEC60529 when used with LR44 alkaline or nickel metal hydride disposable batteries. This water protection rating means that the sound processor with the Aqua+ can be continuously submerged under water to a depth of up to 3 meters (9 feet and 9 inches) for up to 2 hours. Refer to the relevant User Guide for more information.



Tip

Demonstration vs. implantable bone conduction solution

Counsel patients about the expected improvement in sound quality a patient can receive with a surgical bone conduction solution like an Osia System, compared to a demonstration with non-surgical solution using the Baha 6 Max Sound Processor.⁹ A surgical solution has direct access to the bone conduction path with no skin attenuation to overcome. Additionally, Osia technology is uniquely suited to transmitting high frequency sounds to help patients hear better, especially in challenging situations like noisy environments.^{2,10}



Patient fitting and monitoring

Goals

- Provide audibility and access to speech with comfortable wear for the child to use the device to the maximum potential



Device registration

Fill out registration card available in the surgical and/or processor docupacks —OR— log in to myCochlear Professional portal to register devices.



Remote Assist for Baha 6 Max Sound Processors*

Your patient, your care, anywhere

With Cochlear Remote Care, offer your patients the convenience of quality hearing care without the need to visit the clinic. Manage patient progress and offer programming to those who may be limited by location, health, mobility, or school/work commitments.

- With Cochlear Remote Assist*, your patients with Baha 6 Max Sound Processors can meet you via a video appointment through their Baha Smart App, allowing you to connect to their sound processor through the Baha Fitting Software.
- You will have access to all software features, such as BC Direct, Feedback Analyzer, programs and processor settings, allowing you to complete a full fitting, upgrade fitting or perform troubleshooting.
- Remote Assist can be fit anywhere into your clinical model to supplement in-clinic care.

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Recommended activation interval

Osia System

4–6 weeks post-surgery

Baha Start

Immediately

Baha Connect

12 weeks post-surgery



Recommended follow-up intervals⁵

- 1 month
- 3 months
- 6 months
- 9 months
- 12 months
- 18 months
- 24 months
- Then annually

Note: Please take age and developmental needs of the child into account when planning post-activation follow-up. For example, a young infant or child may need more extensive follow-up, while an older child or teenager may follow a more adult-type follow-up schedule.

Additional

- Follow-up as needed based on clinical judgement or patient request for clinical management or troubleshooting
- Upgrade as appropriate

Equipment

Verification and validation

- Audiometric test equipment with soundfield capability
- Reinforcers and toys used for Visual Reinforcement Audiometry (VRA) testing and Conditioned Play Audiometry (CPA)
- Recorded speech material

For verification of Baha 6 Max

- Audioscan® Verifit2®
- Audioscan Skull Simulator

Osia System

- Cochlear Osia Fitting Software installed on fitting computer
- Hi-Pro® 2 wired interface with the Cochlear CS45 fitting cables
- NOAHlink® Wireless Programming Interface

Baha System

- Cochlear Baha Fitting Software installed on fitting computer
- NOAHlink Wireless Programming Interface



Site check

Osia System

- Check magnet strength and skin under magnet for redness, irritation, or indentation

What to look for

The magnet fits strong enough to stay on the head but is not too tight that it causes discomfort, soreness, or irritation of the skin.

If skin compression, irritation, or hair loss is present, reduce magnet strength.

If required magnet strength is in-between, consider fitting the strong magnet strength with a Cochlear SoftWear™ pad.

Baha Start

- Check fit and placement of Softband or SoundArc

What to look for

The connector disc fits flush and close-fitting against the skin to ensure effective sound transmission but does not cause discomfort.

Softband: Be able to fit one finger between the head and the Softband.

SoundArc: Adjust the shape so it does not wobble and the soft tip rests slightly in front of the ear on both sides.

Baha Connect

- Check skin around abutment for irritation or infection

What to look for

Redness, inflammation, soreness at site.

Regular cleaning is the most effective way to prevent skin reactions. Patients who are not able to appropriately conduct their own skin care should get assistance from their family or caregiver.

Counsel the patient/caregiver to perform regular site checks.

The patient should contact the clinic immediately if they experience any pain, soreness, itching or warmth, notice redness or irritation at the implant site, or notice the Baha Connect abutment is loose.

Tip

The Baha 6 Max Sound Processor with the LowPro snap coupling is suitable for most patients, but the 2mm Extended snap coupling may be considered for patients requiring additional clearance.



Verification of Baha 6 Max Sound Processors

Verification of the device and the fitting is recommended to ensure audibility and comfort. Scan the QR code to access the Bone conduction verification guide (BUN1029).

Technical measurement for Baha 6 Max Sound Processors

The Technical Measurement workflow in Baha Fitting Software 6.1 will set up the sound processor to allow you to measure and compare the device to the published specification using Audioscan Verifit and Skull Simulator.

SpeechMap® using the Audioscan® Verifit2® and Skull Simulator for Baha 6 Max Sound Processors

Verification of fitting using the Audioscan Verifit2 and Skull Simulator simulates a “real head” response so you can run test measures using the programmed sound processor to view force output, gain and other acoustic attributes and predict patient performance.



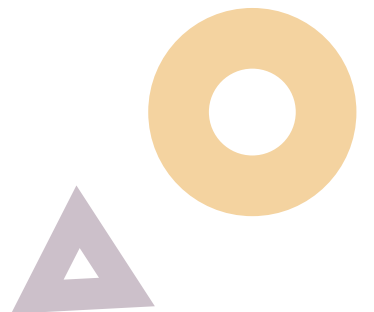
Scan QR code or visit www.cochlear.us/BCVerification to learn more.

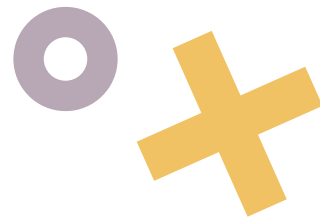


Fitting prescription considerations

BC Direct thresholds obtained using the bone conduction device are recommended to use as a basis for the fitting prescription.⁵ BC Direct thresholds account for the child’s individual skull resonance properties and/or and skin transmission differences and specific device characteristics.

However, obtaining BC Direct thresholds may not be developmentally feasible with infants and young children. If BC Direct thresholds are not available, use audiometric or ABR bone conduction thresholds. At least one low- and one high-frequency bone conduction threshold is necessary for the fitting.⁵ As soon as the child is developmentally capable, measure BC Direct thresholds and update the fitting prescription.





Activation/upgrade fittings

Site check

- Complete site check as appropriate for device

Programming

- Complete programming workflow for a first fitting
- Complete Verification (optional)
- Enable datalogging to review at the next visit

Counseling considerations

- Counsel on proper site maintenance and reporting of symptoms
- Practice attaching and taking off device and review basic device use
- Review the activation kit and introduce accessories based on the child's hearing, educational, and extracurricular needs
- Provide Recipient Solutions Manager contact information (www.cclr.me/welcome)
- Set up the Baha or Osia Smart App and create a Cochlear Account for the carers and the child (if age appropriate)



Follow-up visits

Site check

- Complete site check as appropriate for device

Programming

- Review datalogging
- Complete programming workflow for a follow-up fitting as needed
- Measure BC Direct thresholds and update fitting prescription as needed
- Complete outcomes evaluation as appropriate

Counseling considerations

- Counsel family based on the findings of the site check, datalogging, programming, and outcomes evaluation
- Re-train on device and accessory use and maintenance as needed



Validation of fitting

To validate the fitting on the child, outcomes measures allow comparison to the pre-treatment baseline as well as previous post-fitting intervals to monitor performance and serve as a point of discussion in post-treatment counselling.

- Conduct an aided evaluation in the soundfield
 - Isolate the test ear through plugging, muffing, or masking the non-test ear as appropriate for the child and indication
 - Evaluate performance with fitted bone conduction device using frequency-specific and/or speech stimuli
- Questionnaires (hearing, communication, quality of life)
- Compare aided testing to unaided baseline at candidacy evaluation
- Compare aided testing to last visit

Aided soundfield testing of fitted device

Depending on the age and/or developmental capabilities of the child:

- Behavioral audiometry to measure thresholds from 500 Hz through 6000 Hz using narrow band noise stimuli
- Consider measuring aided thresholds with the Ling 6(HL) test (v2.0)⁷ with calibrated, pre-recorded Ling 6 sounds
- Speech audiometry (threshold and suprathreshold)

Tip

The same measures used for candidacy can be used post-fitting to validate the fitting and allow comparison to the pre-treatment baseline as well as previous post-fitting intervals.

Tip

All day wear and impact on speech and language development:

School age children spend most of their time listening to the speech of other children and women, which has more emphasis on high frequency content¹⁰

They are exposed to more complex listening environments¹⁰

They need consistent access for the full range of speech sounds¹¹

They have a desire for more aesthetically pleasing or more discreet solution¹²

Selecting the most appropriate hearing technology based on the child's changing needs is critical to their hearing success¹⁰

Next steps on the child's hearing journey

Goals

- Determine appropriate bone conduction solution
- Help the family navigate the upgrade or surgical solution transition process
- Prepare the family for the device fitting appointment



Check your patient's eligibility for sound processor replacement through insurance

The device is out of warranty AND one of the following:

- The device is lost or stolen
- Medical necessity is described including current impact on activities of daily living
- The device is broken and retired or obsolete (normal process as technology advances)



How do I know if my patient should transition to a surgical solution?

- Child would benefit from direct access to the bone conduction path with no skin attenuation to overcome
- Child would benefit from additional gain in high frequencies
- Child's hearing loss has progressed
- Child would benefit from a solution without daily skin maintenance
- Child meets age requirement for surgical solution
- Child and family are motivated to proceed with surgical solution
- Child desires more discreet or aesthetically pleasing solution
- Child and family desire a solution designed to minimize feedback—also making hats, helmets, and headgear easier to wear.

Contact Cochlear

T 800 523 5798
 E customer@cochlear.com
www.mycochlear.com
www.cochlear.us/rsm
www.cochlearstore.com

Resources

www.cochlear.us/upgradesforprofessionals
www.cochlear.us/orderform



3 pathways

- 01 Upgrade to new sound processor technology - OR - New or Replacement Baha Start system
- 02 Transition from non-surgical bone conduction solution to surgical bone conduction solution
- 03 Transition from an implantable solution to a new or different Cochlear implantable solution



Next steps

Bone conduction solution determination

See sections: Bone conduction demonstration evaluation (page 8), and Bone conduction treatment determination (page 10)

- Complete a bone conduction evaluation using child's current device
- Determine treatment pathway, taking into consideration evaluation results, age, patient factors, health plan benefits and coverage, and readiness for surgery

Placing the order

Transitioning to a surgical solution

Step 1: Schedule surgery

Step 2: Fill out the new system order form and submit to Cochlear

Sound processor replacement

Patient initiated

Patient calls Cochlear or places order via online store —OR— patient schedules a virtual consultation with a Cochlear Upgrade Solution Specialist

Clinic initiated

Fill out the upgrade or replacement order form and submit to Cochlear

Cochlear may review specific patient and insurance requirements and provide you with a Letter of Medical Necessity (LMN) template.

Device fitting

See sections: Remote Care for patients with a Baha 6 Max Sound Processor and Patient fitting and monitoring (page 14)

- Determine if the fitting will be through Remote Assist* or in clinic
- Schedule your patient for their fitting appointment
- Complete the fitting

* Remote Assist for Baha for compatible Baha sound processors is intended for a follow-up adjustment or setup of a replacement or upgrade sound processor for suitable qualified patients based on clinical judgment. Only available at clinics that have enrolled in Remote Care. For compatibility information visit www.cochlear.com/compatibility.

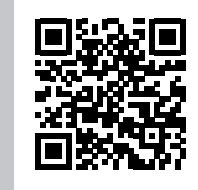
Billing and coding

The codes in this section may be reported by audiologists and other licensed clinicians for services related to pre- and post-operative analysis and rehabilitation of auditory osseointegrated (AOI) patients.

This list is not intended to be comprehensive of all services that may be offered to AOI patients.

Additional coding support

T 800 587 6910
 E codingsupport@cochlear.com
 www.cochlear.us/reimbursementhub



Evaluation

The following codes may be applicable based on documentation of the services listed.

92550*	Tympanometry and reflex threshold measurements
92557*	Comprehensive audiometry threshold evaluation and speech recognition
92626*†‡Δ#	Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); first hour
92627*†‡Δ^	Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); each additional 15 minutes



Fitting

The following codes may be applicable based on documentation of the services listed. As of January 2024, there are two new Current Procedural Terminology (CPT®) codes to report services related to the diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor.

92622#†	Diagnostic analysis, AOI sound processor; 1st hour
92623^	Diagnostic analysis, AOI sound processor; each additional 15 min
V5011	Fitting/Orientation/Checking of hearing aid
Remote Care~	Coverage for audiology telehealth visits may vary by payer; contact payer to determine benefit coverage details



* Audiometric tests identified by codes 92550–92597 include testing in both ears. Use modifier -52 if only one ear tested.
 ‡ Swanson N. Do's and Don'ts for revised implant-related auditory function evaluation CPT Codes. ASHA Leader, Aug 31, 2020.
 †‡ The descriptions for 92626 and 92627 were revised in 2020. Please see ASHA article "New and Revised CPT Codes for 2020" https://www.asha.org/practice/reimbursement/coding/new_codes_aud/ for details of changes and proper use of the codes.
 Δ Perform to assess changes in speech perception, discuss process and update rehab plan.
 # Providers should check with payers for additional billing guidance on the use of modifiers with code pair 92622/92626. Within the CPT Manual parenthetical for CPT codes 92622/92623, guidance states these codes cannot be reported together with CPT 92626/92627. Per NCCI edits, bundled into 92622 if performed on the same day. Use -59 modifier if the procedure is separate and distinct from primary service.
 † 92622 and 92626 require a minimum of 31 minutes. For less than 31 min, use unlisted code 92700.
 ^ 92623 and 92627 require a minimum of an additional 8 minutes.
 ~ Medicare's telehealth list will not include the new AOI codes for inclusion in 2024. Providers are encouraged to collaborate with professional societies to communicate their desire for continued access to telehealth services.



Hear now. And always

Cochlear is dedicated to helping people with moderate to profound hearing loss experience a world full of hearing. As the global leader in implantable hearing solutions, we have provided more than 750,000 devices and helped people of all ages to hear and connect with life's opportunities.

We aim to give people the best lifelong hearing experience and access to next generation technologies. We collaborate with leading clinical, research and support networks to advance hearing science and improve care.

That's why more people choose Cochlear than any other hearing implant company.

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This material is intended for health professionals. If you are a consumer, please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always read the instructions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

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