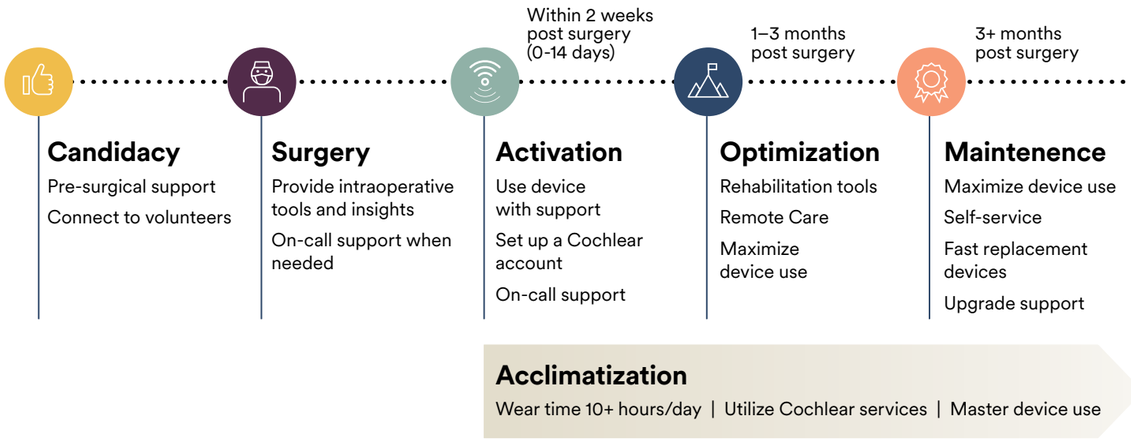
Cochlear™ Nucleus® System

Adult cochlear implant protocol

Contents

Cochlear care model

Inspired by connecting people with care throughout their journey



Candidacy evaluation

Session goals

01 Complete audiometric testing

02 Verify hearing aid fitting and satisfaction

03 Evaluate aided speech recognition to determine cochlear implant (CI) candidacy

04 Determine treatment recommendations

Tip

If the patient has Unilateral Hearing Loss (UHL)/Single-Sided Deafness (SSD), please refer to the Single-Sided Deafness Clinical Recommendations White Paper FUN4699.

Minimum tasks

Evaluate hearing status

- ☐ Diagnostic audiogram

Determine benefit and satisfaction with optimized hearing aids

- ☐ Verification of amplification (e.g., Real Ear Measurement)
  - If hearing aids are not meeting targets, consider fitting a clinic loaner hearing aid
- ☐ Patient-reported outcome questionnaires (e.g., SSQ or other)

Evaluate aided speech recognition to determine cochlear implant candidacy

- ☐ Aided speech perception testing on each ear using optimized amplification
  - Refer to the Minimum Speech Test Battery 3 (MSTB-3) for detailed instructions

Determine treatment recommendations

- ☐ Determine if the patient meets candidacy guidelines for cochlear implants
- ☐ Consider other factors which may impact candidacy and counsel appropriately (e.g., etiology, cognitive status, duration of deafness, patient goals)
- ☐ Make one of the following treatment recommendations:
  - If they are a candidate for a cochlear implant, refer the patient for a medical evaluation
  - If they are not a candidate, provide them with information about cochlear implants and recommend they return for re-evaluation in one year
  - If they are not a candidate and their hearing aid was not optimized at the time of evaluation, consider referring back to hearing aid dispenser and re-evaluating as appropriate
  - If they are a candidate and elect not to move forward, provide them with information about cochlear implants and consider a re-evaluation within one year

Counseling suggestions:

- ☐ Explain the hearing loss, current aided benefit, and expected thresholds with a cochlear implant (i.e., detection thresholds at 25 dB HL at 250-6000 Hz)
- ☐ Confirm for the patient that candidacy determination indicates that hearing performance will be better with a cochlear implant than hearing aids for the majority of patients with their hearing profile
- ☐ Discuss how improved hearing with an implant will help the patient reach their goals
- ☐ Explain next steps, including medical evaluation
- ☐ Discuss how Remote Care can be part of the patient's care journey
- ☐ Connect the patient to a recipient; your Cochlear Engagement Manager is available to connect the patient to a volunteer, if desired

Supporting services and materials

For the hearing professional:

- Audiology on Call (AOC) – call **1 877 883 3101**
- Minimum Speech Test Battery 3 (MSTB-3) Protocol Manual and forms
- Cochlear Demo Kit
- Treatment Options Placemat FUN5049

For your patient:

- Cochlear Engagement Manager QR Code (this can be obtained from your local field staff)
- Candidate Guide FUN2646
- Audiologist appointment guide for patients FUN2412
- Cochlear Implant Counseling Guide FUN4347
- Preparing for surgery guide FUN2590

Pre-surgical

The Pre-surgical visit may take place any time before surgery or during the candidacy visit.

Session goals

01 Establish expectations

02 Complete the order form

03 Establish any baseline outcome measures not completed during the candidacy testing

Tip

The pre-surgical visit can be accomplished in many ways. Consider utilizing telehealth, Cochlear Engagement Manager or Audiology Tech to support this interaction. This step may also be included in the Candidacy Evaluation.

Minimum tasks

Establish expectations

- ☐ Explain to the patient what will happen before, during and after surgery
  - Inform the patient they will acclimate to sound best if they use their device regularly (at least 10+ hours per day) and master device use
  - After surgery, when the patient's device has been registered, patients can download their Nucleus Smart App and create a Cochlear Account once their device has been registered
  - How they will maximize hearing in everyday situations (e.g., discuss bimodal hearing, bilateral CI)

Complete order form

- ☐ Select processor(s), colors and accessories based on the patient's preferences and hearing goals
- ☐ Request an acoustic component if there is potential to utilize post-operative residual hearing in the ear to be implanted. (i.e. low frequency thresholds through 500 Hz better than or equal to 60 dB HL)
- ☐ A Smart Bimodal order form is available if the patient will be ordering a bimodal hearing aid at the time of surgery
- ☐ Link to Cochlear order forms is here

Outcome measures (if not yet completed)

- ☐ Administer patient reported outcome questionnaires (e.g., SSQ-12, CI-QOL, COSI) and review results with patient
- ☐ Complete any speech perception testing from the Minimum Speech Test Battery 3 (MSTB-3) that has not already been completed

Counseling suggestions

As your patient prepares for surgery, they will have many questions. Consider the following counseling topics:

- ☐ Benefits of bimodal hearing and Smart Bimodal solutions (if appropriate)
- ☐ Discuss follow up care using a combination of Remote Care* and in-person care
- ☐ Answer any questions about the surgical process
- ☐ Discuss the goals the patient has for treatment (e.g., using COSI)

Supporting services and materials

For the hearing professional:

- Pre-Operative Candidacy and Counseling Tool FUN2855

For your patient:

- Create a Cochlear Account
- Cochlear Engagement Manager
- Guide to Prepare for Surgery FUN2590

* Remote Check and Remote Assist for Nucleus sound processors are intended for ages 6 and older. Remote Check and Remote Assist features are only visible and accessible if they are enabled by a clinician. Clinicians should consider the suitability of the feature before enabling Remote Check and Remote Assist. Remote Check does not replace clinical care and does not involve remote programming of the sound processor. Only available at clinics that have enrolled in Remote Care. For sound processor and app compatibility information visit www.cochlear.com/compatibility

Activation

Initial activation takes place one to four weeks after surgery.

Session goals

01 Confirm status of the implanted ear

02 Ensure a minimum dynamic range of 40 CL

03 Ensure C levels are set to “loud”

04 Ensure audibility of soft sounds

05 Set expectations of wear time of 10+ hours per day

Minimum tasks

Confirm status of the implanted ear

- ☐ Complete unaided air conduction thresholds in the implanted ear if hearing thresholds were 70 dB HL or better below 1000 Hz
- ☐ Since hearing thresholds may continue to shift up to one month after surgery, ensure residual hearing is tested/re-tested at least once after one month post-surgery
  - If thresholds remain 70 dB HL or better through 500 Hz, consider electroacoustic fitting (please refer to the EAS Fitting Flow FUN1979 for further guidance)
- ☐ Review surgical data (e.g, operative note, intraoperative test results)
- ☐ Inspect implant site, ear canal and area behind pinna for any issues (e.g., redness, pain, earache, discharge) and select correct magnet strength to obtain balance between comfort and retention

Create an initial MAP

- ☐ Create an initial MAP using population mean*
- ☐ Go “On Air” with the initial MAP
- ☐ Raise T and C profile using default step size until the patient reaches a final level of “loud”; this may take several minutes as the patient habituates to electrical stimulation
- ☐ In the Comfort Screen, sweep at C levels in bands
- ☐ Stimulation should be “loud” for each band to ensure broadly equivalent loudness across the frequency range
  - Programming to “loud” is specific to activation and the acclimation phase; in the optimization phase, “loud but comfortable” may be used since the patient will acclimate to sound during early device use

* Alternatively, clinicians may use objective measures such as Electrical Stapedius Reflex Thresholds ESRT and/or Neural Response Telemetry NRT with a Dynamic Range of 40-60 clinical units to set the initial MAP

Ensure audibility

- ☐ May use Ling sounds or other informal measures to confirm audibility

Program the sound processor

- ☐ In the Finalize screen, modify the default settings as follows:
  - Program Slot 1: SCAN 2 FF
  - Program Slot 2: SCAN 2
- ☐ In Processor Settings, allow ForwardFocus and Master Volume Bass and Treble (MVBT) as this will enable the patient to self-manage their sound tolerance and sound quality. (Provision of progressive MAPs is not recommended if Population Mean was used)

Address hearing needs in the contralateral ear

- ☐ Link Smart Bimodal device, if applicable (see the Bimodal Fitting Flow in the Custom Sound Pro Help menu for further details, and visit www.cochlear.com/compatibility for a list of compatible Smart Bimodal devices)
- ☐ If the patient is using a cochlear implant in the opposite ear, informally check for equal loudness between the two ears. (Further loudness balancing may be completed during the optimization phase). Continued full time device use of both sides is recommended

Enroll the patient in Remote Care

- ☐ Enroll the patient in Remote Care
- ☐ Prior to next visit, assign a “baseline” check to include Impedances, Datalogging, Implant Site Photo and Aided Threshold Testing (ATT) with additional options as needed

Counseling suggestions

- ☐ Set a goal of full time use of the device (10+ hours per day) and let the patient know you will be reviewing datalogging with them at future visits
- ☐ Go over basic functionality of the sound processor (processor and coil on head, attach battery, charge batteries, on/off, change program, change volume, utilize MVBT)
- ☐ Introduce aural rehabilitation options
- ☐ Ensure the patient is ready for Remote Care (has downloaded their Nucleus Smart App and created a Cochlear Account. For smartphone compatibility, please see www.cochlear.com/compatibility)
- ☐ Sign the patient up for their session with the Cochlear Recipient Solutions Manager (RSM)
- ☐ Confirm next appointment and/or Remote Check

Supporting services and materials

For the hearing professional:

- Programming Report Template FUN5075
- Adult Loudness Scaling Chart FUN2003
- Getting Started with Remote Care (Professional) FUN4669
- Initial Activation Guide FUN5132
- Electroacoustic (EAS) Fitting Flow FUN1979

For your patient:

- Cochlear Recipient Solutions Manager (RSM)
- Getting Started Guide(s)
- Getting Started with Remote Care (Patient) FUN3956
- Adult Rehabilitation Manual FUN3570
- Cochlear CoPilot

Tip

Consider utilizing another professional to assist with the device use and/or counseling when applicable (e.g., Audiology Tech, Speech-Language Pathologist, Cochlear Recipient Solutions Manager (RSM), etc.)

Optimization

Follow up betwween 30 and 90 days after activation.

Session goals

01 Confirm audibility and appropriate loudness

02 Inspect implant site and equipment

03 Confirm consistent wear time (minimum 10 hours per day)

04 Evaluate progress informally or formally

05 Optimize the MAP as indicated

Minimum tasks

Inspect the implant site and equipment

- ☐ Ensure the incision site is healing well. Look for signs of redness or swelling and ask about soreness. Any medical concerns should be referred to the patient's surgeon for further follow up
- ☐ Inspect the scalp area beneath the magnet to ensure the magnet is not too tight or too loose
- ☐ Perform listening check of the sound processor microphone and ensure microphone covers are clean and free of debris

Check for audibility

- ☐ Before any testing, confirm equipment is functioning
- ☐ Perform a sound-field audiogram or review the Aided Threshold Test (ATT) in Remote Check to ensure soft sounds are audible to the patient
- ☐ Results should be 25 dB HL or better

Evaluate progress

Progress may be evaluated in different ways depending on how long the patient has been using their device during the optimization phase. Consider the following options:

- ☐ Up to one month:
  - Informal speech perception measures (e.g. common phrases, numbers)
  - Review and discuss datalogging
- ☐ One to three months:
  - CNC Words in the implanted ear and in the everyday listening condition or Digit Triplet Test if using Remote Check
  - AzBio sentences with a +10 SNR in the everyday listening condition
  - Patient-reported satisfaction measure (e.g., SSQ, CI-QOL)

Please refer to the Minimum Speech Test Battery 3 (MSTB-3) for details on post-operative testing recommendations.

Review datalogging

- ☐ Consider wear time, time in speech, program use, daily environments, and speech recognition outcomes (if tested) when determining if MAP changes are needed and when making treatment and rehabilitation recommendations
- ☐ Use datalogging results to counsel the patient on device use as needed (Wear time of 10+ hours per day is recommended)[4]

Optimize the MAP

T levels:

- ☐ Measure T levels at least once during this phase, ensuring that they are set at the lowest electrical stimulation that is 100% audible
- ☐ After they have been measured once, T levels should only need to be re-assessed if indicated by audibility testing:
  - Sound-Field: Re-measure T's if thresholds are poorer than 25 dBHL when using warble tones
  - Remote Check: Re-measure T's if thresholds are poorer than 20 dBHL

C levels:

- ☐ Cross check using Electric Stapedial Reflex (ESRT). As a general rule, C levels are set approximately 15 CL below the ESRT threshold[5–7]
- ☐ If ESRT is not available, sweep in bands to ensure that all C levels are equal in loudness

Processor Settings:

- ☐ Review processor settings based on patient usage and datalogging

Tip

Neural Response Telemetry (NRT) can be measured at least once during the optimization phase to provide a physiologic baseline of neural response to electrical stimulation. NRT thresholds are typically audible and fall between T and C levels on established MAPs of the same pulse width.[1]

Address hearing needs in the contralateral ear

Bimodal:

- ☐ If the patient is using a Smart Bimodal solution, refer to the Bimodal Fitting Flow in the Custom Sound Pro Help menu for further details on optimization and visit www.cochlear.com/compatibility for a list of compatible Smart Bimodal devices
- ☐ Consider whether bilateral implantation is appropriate for the patient based on their reported bimodal benefit and/or based on the speech recognition obtained in the best aided condition of the non-implanted ear.[2] If unsure, ask the patient[8]

Bilateral CI:

- ☐ Balance the loudness of the MAPs between ears using Custom Sound Pro software

Remote Care

Remote Care (i.e., Remote Check and Remote Assist) should be introduced to the patient in the optimization phase. Examples of uses include:

- ☐ Confirm audibility, evaluate hearing performance, impedances and review datalogging with Remote Check
- ☐ Individual ear testing that enables isolation of the implanted ear in patients with Unilateral Hearing Loss (UHL) and Single-Sided Deafness (SSD)
- ☐ Interim evaluation of performance and checking of device with Remote Check and/or global adjustment in lieu of in-person appointments with Remote Assist
- ☐ Troubleshooting

Counseling suggestions

- ☐ Review progress and let the patient know how they are doing
- ☐ Ensure the patient is ready for Remote Care
- ☐ Discuss ongoing aural rehabilitation and provide more support as needed (Hearing Therapy & Rehabilitation Resources)
- ☐ Review any accessory usage and schedule with the Cochlear Recipient Solutions Manager (RSM) for orientation and support
- ☐ Encourage the patient to engage with Cochlear's New Recipient Welcome email program for early device use support

Supporting services and materials

For the hearing professional:

- Evaluation Report Template FUN5076
- Programming Report Template FUN5075
- Adult Loudness Scaling Chart FUN2003
- Getting Started with Remote Care (Professional) FUN4669

For your patient:

- Getting Started Manuals for sound processors FUN4761_ and FUN3946
- Rehabilitation Resources Website
- Cochlear YouTube Channel
- Cochlear Recipient Solutions Manager (RSM)
- Getting Started with Remote Care (Patient) FUN3956

Maintenance

Maintenance typically begins 90+ days from activation as performance typically plateaus during this timeframe[4]

Session goals

01 Monitor and review hearing goals using patient satisfaction outcomes

02 Evaluate changes in hearing and/or lifestyle. Determine need for further support, including rehabilitation, bilateral CI, sound processor upgrade eligibility, etc.

Tip

Patients should enter the maintenance phase when:[9–10]

- Post-operative CNC word score in the implanted ear is **56% or better**

OR

- The patient's scores in the implanted ear have **improved by at least 20%** when compared to scores obtained in that ear prior to implantation

If the patient has not yet met these milestones or if other concerns exist, they can remain in the optimization phase for further support. Consider consultation with Cochlear Clinical Support (e.g., Cochlear Representative or Audiologist on Call) if needed.

Minimum tasks

Perform with Remote Care whenever possible

Measure the patient's progress

☐ Perform the following outcome measures:

- Audibility: Thresholds measured with Aided Threshold Test (ATT) in Remote Check should be 20 dBHL or less and thresholds measured in the soundfield should be 25 dBHL or less
- Datalogging: Device use should be 10 or more hours per day
- Speech Perception Testing (e.g., Digit Triplet Test [DTT] or tests listed in the MSTB-3)
- Patient satisfaction (e.g., SSQ, CI-QOL)

Check progress against previous test results

☐ Confirm that current results are stable or improved when compared to previous test results. Changes considered to be significant for commonly used tests include:

- CNC Words: 15% change
- AzBio Sentences: 15% change
- Digit Triplet Test (DTT): 3 dB change[3]

Adjust programs if needed

☐ Assess the patient's goals and consider whether additional features or accessories are warranted

☐ Re-adjust T and C levels ONLY if there are changes to audibility and/or performance and proper equipment function has been verified

☐ Consider any technology changes since the patient's last visit (e.g., firmware updates)

Counseling suggestions

☐ Re-educate the patient on equipment as needed

☐ Encourage the patient to take advantage of Cochlear resources

☐ If the patient is a unilateral recipient, consider the opposite ear and whether ongoing bimodal support is needed or whether patient may need a bilateral implant based on their report

☐ Consider whether the patient is ready for an upgrade (e.g., their current processor is 5+ years old)

☐ Encourage the patient to connect with Cochlear through Cochlear Family and/or social media for ongoing updates and support

Supporting services and materials

For the hearing professional:

- Programming Report Template FUN5076
- Audiologist on Call (AOC)– call **1 877 883 3101**
- Getting Started with Remote Care (Professional) FUN4669
- Clinic Upgrade Protocol FUN4769

For your patient:

- Getting Started with Remote Care (Patient) FUN3956
- Upgrade Process FUN4432

Appendix

Billing and coding

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
92584[†^]	Electrocochleography
92603[§]	Diagnostic analysis of cochlear implant, age 7 years or older: with programming
92604[§]	Diagnostic analysis of cochlear implant, age 7 years or older: with subsequent programming
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
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

For additional coding support, please call 1-800-587-6910 or email codingsupport@cochlear.com

* Audiometric tests identified by codes 92550–92597 include testing in both ears. Use modifier -52 if only one ear tested.

† https://www.audiology.org/audiology-today-mayjune-2020/coding-and-reimbursement-specialty-series-cochlear-implants

^ Per CCI edits, bundled into 92604 if performed the same day. (Unable to use the -59 modifier)

§ Append -52 modifier to CPT 92603 or 92604 to denote reduced services when provided via telehealth. Check with payer for appropriate telehealth and place of service. For more information on coverage for Remote Care, see “Reimbursement Considerations for Cochlear Remote Care Solutions” (CAM-HE-033_G)

‡ 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.

Per CCI edits, bundled into 92604 if performed the same day. Use -59 modifier if the procedure is separate and distinct from primary service.

Δ Perform to assess changes in speech perception, discuss process and update rehab plan

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 700,000 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.

References:

1. Botros A, Psarros C. (2010) Neural response telemetry reconsidered I: The relevance of ECAP threshold profiles and scaled profiles to cochlear implant fitting. Ear Hear. Jun;31(1):367-79. doi: 10.1097/AUD.0b013e3181c9fd86
2. Gifford RH, Dorman M. (2019) Bimodal hearing or bilateral cochlear implants? Ask the patient. Ear Hear. May/Jun;40(3):501-516. doi: 10.1097/AUD.0000000000000657.
3. Maruthurkkara S, Case S, Rottier R. Evaluation of Remote Check: A Clinical Tool for Asynchronous Monitoring and Triage of Cochlear Implant Recipients. Ear Hear. 2021 Jul 27.
4. Holder JT, Dwyer NC, GIfford RH (2020) Duration of processor use per day is significantly correlated with speech recognition abilities in adults with cochlear implants. Otol Neurotol, 41(2):e227-e231.
5. Holder et al (2023) Cochlear implant upper stimulation levels: ESRT vs loudness scaling. Otol Neurotol, 44(9):e667-e672
6. Cache P et al (2021) The long-term stability of the electrical stapedial reflex threshold. Otol Neurotol. 42(1)
7. Holder JT (2023) ACIA 2023, Dallas, TX
8. Berg KA, Holder JT, Gifford RH. (2023) Development of an optimized protocol for cochlear implant care to increase cochlear implant access. Otol Neurotol Sep 1;44(8):e635-e640. doi: 10.1097/MAO.0000000000003968.
9. Clinical Evaluation of the Nucleus CI532 Cochlear Implant in Adults 2019: Internal Analysis
10. Buchman, et al (2020) Assessment of speech understanding after Cochlear Implantation in adult hearing aid users. JAMA Otol Head & Neck Surg, doi:10.1001/jamaoto.2020.1584

For information regarding the sound processors, implants, operating systems and devices that are compatible with Cochlear's Remote Care services, visit www.cochlear.com/compatibility

For further reimbursement guidance, please see: https://www.asha.org/practice/reimbursement/medicare/aud_coding_rules/

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.

ForwardFocus can only be enabled by a hearing implant specialist. It should only be activated for users 12 years and older who are able to reliably provide feedback on sound quality and understand how to use the feature when moving to different or changing environments. It may be possible to have decreased speech understanding when using ForwardFocus in a quiet environment.

Remote Check and Remote Assist for Nucleus sound processors are intended for ages 6 and older. Remote Check and Remote Assist features are only visible and accessible if they are enabled by a clinician. Clinicians should consider the suitability of the feature before enabling Remote Check and Remote Assist. Remote Check does not replace clinical care and does not involve remote programming of the sound processor. Only available at clinics that have enrolled in Remote Care.

SNR-NR, WNR and SCAN are approved for use with any recipient ages 6 years and older who is able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance 2) report a preference for different program settings.

Visit www.cochlear.us/ReimbursementHub for the most recent resources for coding, coverage, payment, and advocacy for cochlear implant, bone conduction, and connected care solutions.

Cochlear Americas
10350 Park Meadows Drive, Lone Tree, CO 80124, USA
Tel: +1 303 790 9010 Support: Tel: +1 800 483 3123

Cochlear Canada Inc.
2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 800 483 3123 Fax: +1 416 972 5083

www.cochlear.com/us

FUN2802 ISS8 MAY23

Follow us on