NCA - Cochlear Implantation (CAG-00107R) - Decision Memo

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Decision Summary

The Centers for Medicare & Medicaid Services (CMS) is reconsidering the national coverage determination established at section 50.3 of the Medicare National Coverage Determinations manual. We are expanding coverage by broadening the patient criteria and removing the requirement that for individuals with hearing test scores of > 40 % and ≤ 60 %, cochlear implantation may be covered only when the provider is participating in and patients are enrolled in either an FDA-approved category B IDE clinical trial, a trial under the CMS Clinical Trial Policy, or a prospective, controlled comparative trial approved by CMS. We have concluded that the evidence is sufficient to determine that cochlear implantation may be covered for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence cognition. Patients must meet all of the following criteria.

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
- No contraindications to surgery; and
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

CMS may also provide coverage of cochlear implants for beneficiaries not meeting the coverage criteria listed above when performed in the context of FDA-approved category B investigational device exemption clinical trials as defined at 42 CFR 405.201 or as a routine cost in clinical trials under section 310.1 of the National Coverage Determinations Manual titled Routine Costs in Clinical Trials.

See Appendix B for the draft manual language.

Decision Memo

TO: Administrative File: CAG-00107R

SUBJECT: Reconsideration—Final National Coverage Determination for Cochlear Implantation

DATE: September 26, 2022

I. Decision

The Centers for Medicare & Medicaid Services (CMS) is reconsidering the national coverage determination established at section 50.3 of the Medicare National Coverage Determinations manual. We are expanding coverage by broadening the patient criteria and removing the requirement that for individuals with hearing test scores of > 40 % and ≤ 60 %, cochlear implantation may be covered only when the provider is participating in and patients are enrolled in either an FDA-approved category B IDE clinical trial, a trial under the CMS Clinical Trial Policy, or a prospective, controlled comparative trial approved by CMS. We have concluded that the evidence is sufficient to

determine that cochlear implantation may be covered for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence cognition. Patients must meet all of the following criteria.

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
- No contraindications to surgery; and
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

CMS may also provide coverage of cochlear implants for beneficiaries not meeting the coverage criteria listed above when performed in the context of FDA-approved category B investigational device exemption clinical trials as defined at 42 CFR 405.201 or as a routine cost in clinical trials under section 310.1 of the National Coverage Determinations Manual titled Routine Costs in Clinical Trials.

See Appendix B for the draft manual language.

II. Background

Throughout this document we use numerous acronyms, some of which are not defined as they are presented in direct quotations. Please find below a list of these acronyms and corresponding full terminology. Included in this list are the acronyms for various assessment tools that are noted in this document as measures used to evaluate hearing loss. For the convenience of the reader, references are provided in the bibliography to further describe each measure.

APHAB - Abbreviated Profile of Hearing Aid Benefit
AzBio Sentence Test - Arizona Biomedical Sentence Test
CI - Cochlear implant
95% CI – 95% Confidence interval
CMS - Centers for Medicare & Medicaid Services
CNC - Maryland Consonant–Nucleus–Consonant word tests
CUNY Sentences - City University of New York Sentences
FDA - Food and Drug Administration
HINT - Hearing in Noise Test
HUI-3 - Health Utility Index Mark 3
Hz - Hertz
MEDCAC - Medicare Evidence Development & Coverage Advisory Committee
NCA - National Coverage Analysis
NCD - National Coverage Determination
NIDCD – National Institute on Deafness and Other Communication Disorders
SNR - signal-to-noise ratio
US - United States

Hearing loss affects approximately 16% of the adult population of the United States, corresponding to 29 million individuals. The impaired ability to communicate with others has been associated with poorer objective physical functioning in older adults, increased risk for disability and a poorer quality of life (Mahboubi, Lin & Bhattacharyya,

2018). Moreover, as compared with age-matched adults with unimpaired hearing, older persons with hearing loss have higher rates of hospitalization, death, falls, dementia and depression, even when known risks for these disorders are taken into account (Cunningham & Tucci, 2017).

Sensorineural hearing loss occurs as a result of damage to the hair cells in the cochlea, or to the auditory nerve (Health Quality Ontario, 2018). Sensorineural problems affect the conversion of mechanical sound to neuroelectric signals in the inner ear or auditory nerve. Presbycusis, or age-related hearing loss, is the most common type of sensorineural loss (Michels, Duffy & Rogers, 2019). Age-related hearing loss is usually bilateral and symmetric and is most pronounced at higher frequencies (≥ 2000 Hz). A prominent feature of this type of hearing loss is reduction in the ability to understand speech even if the sounds are loud enough (Cunningham & Tucci, 2017).

The prevalence of hearing loss increases with age, and approximately two thirds of people 70 years of age or older in the United States exhibit hearing loss. At least 1.2 million adults in the United States live with severe or profound hearing loss — a level of impairment that is not sufficiently corrected with hearing aids (Carlson, 2020). However, there are a number of other devices that can aid in the improvement of hearing, in the appropriate individual. Among them are cochlear implants (NIDCD Fact Sheet Age Related Hearing Loss, 2016).

The mechanism of action of cochlear implants is very different from that of hearing aids. Whereas hearing aids function to amplify sound, cochlear implants bypass nonfunctional or missing cochlear hair cells and directly stimulate the surviving cells of the distal cochlear nerve (Carlson, 2020). There are various cochlear implants available commercially, but the concept of their componentry is similar. In general, the hardware of the implant system consists of both external and internal components. The external components consist of a microphone that detects environmental sound and a speech processor that converts it to electronically encoded signals. The encoded signal is transmitted to the internal receiver across the skin and soft tissues. The transmitted signal continues to the electrode arrays that sit within the cochlea and send electrical stimuli to the cochlear nerve fibers (Naples & Ruckenstein, 2020).

Cochlear implant surgery is a relatively low-risk procedure performed while the patient is under general anesthesia. Though like any surgery, complications might arise. Data indicates that the overall prevalence of complications is approximately 13% (sample size = 7513 patients) and the prevalence of major complications is 2.7% (sample size = 7542). Total device failure requiring reimplantation has been reported in 1.9% of cases (sample size 6461). Other complications include wound infection, surgical site pain, loss of pre-operative functional acoustic hearing, persistent vestibular symptoms and permanent facial nerve paralysis (Carlson, 2020).

Cochlear implants can give the individual a useful representation of environmental sound as well as the ability to understand speech. However, hearing via cochlear implant is different from 'normal' hearing (NIDCD Fact Sheet Cochlear Implants, 2016). After the surgery, there is a period of time when recipients of the implant adjust to the electrical input of the device. Use of the device requires significant therapy to learn or relearn the sense of hearing. Speech-language pathologists and audiologists are frequently involved in this learning process (NIDCD Cochlear Implants, 2021). For the first year after surgery, cochlear implant recipients need to attend several device-programming sessions at which the sound quality and loudness of the implant are adjusted to improve speech recognition. Although the rate at which speech perception improves after cochlear implantation is variable, increases are usually steepest within the first 6 months of use. Progress can be seen up to 3 years after surgery. However, even with a thorough assessment of candidacy for cochlear implantation, as well as systematic rehabilitation post-operatively, currently there is no certain way to predict whether a patient will be one of the up to 16% of adult cochlear implant recipients who will have poor long-term outcomes (defined as a word- or sentence-recognition score of less than 30% at 12 months (Carlson, 2020)).

There is a variability in testing procedures used by clinicians (Dunn et al, 2020; Prentis, Snapp & Zwolan, 2020) to

qualify Medicare beneficiaries for cochlear implantation within the coverage criteria of this NCD. Historically, CMS has required potential candidates for cochlear implantation to be evaluated based on aided sentence recognition performance, though other means of evaluation are recognized (e.g. monosyllabic word recognition) (Varadarajan, Sydlowski, Li, Anne, & Adunka, 2021; Thai et al., 2021; Zwolan & Basura, 2021). However, CMS has not required the use of particular sentence recognition tests (e.g. HINT, AzBio sentences, etc.) in the evaluation of the beneficiary for a cochlear implant, nor have we specified many other testing conditions for this evaluation (e.g. noise vs quiet, monaural vs binaural 'best aided' state, etc.). Still, we are aware that some professionals in the field believe that Medicare's cochlear implantation candidacy requirements may be too restrictive, and thereby result in the exclusion of well-qualified beneficiaries having access to these devices (Zwolan & Basura, 2021).

III. History of Medicare Coverage

Cochlear implants were first covered for adult Medicare beneficiaries in October 1986, supported by the Office of Health Technology Assessment's "Public Health Service Assessment of Cochlear Implant Devices for the Profoundly Hearing Impaired", dated June 30, 1986 (CAG-00107N, 2005; Feigenbaum, 1986). Medicare coverage was expanded to include children in 1992 (CAG-00107N, 2005).

In the period since the original Medicare coverage decision, devices have been improved and there have been gradual changes in the degree of hearing loss for which the Food and Drug Administration (FDA) has approved use of cochlear implants. In 2005, CMS determined that among other criteria, cochlear implantation was reasonable and necessary for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification was defined by test scores of ≤ 40% correct in the best-aided listening condition on tape recorded tests of open-set sentence recognition. For individuals with hearing test scores of > 40 % and ≤ 60 %, CMS determined that cochlear implantation was covered only when the provider was participating in and patients were enrolled in either an FDA-approved category B IDE clinical trial, a trial under the CMS Clinical Trial Policy, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards (CAG-00107N, 2005).

A. Current Request

On October 27, 2020, CMS received a complete, formal request to reconsider NCD 50.3 from Teresa A. Zwolan, Ph.D., Professor, Department of Otolaryngology, Head & Neck Surgery, Director, Cochlear Implant Program, Michigan Medicine and Craig A. Buchman, MD, FACS, Lindburg Professor and Chair, Department of Otolaryngology-Head & Neck Surgery, Washington University School of Medicine. The scope of the request is to expand the coverage from "less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence recognition" to "less than or equal to 60% correct in the best-aided listening condition on tape-recorded tests of open-set sentence recognition".

The formal request letter can be viewed on the CMS website at https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id306.pdf.

This national coverage analysis (NCA) will focus on this request.

B. Benefit Category

Medicare is a defined benefit program. For an item or service to be covered by the Medicare program, it must fall within one of the statutorily defined benefit categories outlined in the Social Security Act. CMS has determined that

cochlear implants fall within the benefit category of prosthetic devices under section 1861(s)(8) under Part B of the Social Security Act.

The Medicare statute also includes specific statutory exclusions from coverage. Section 1862(a)(7) of the Social Security Act states that no payment may be made under part A or part B for any expenses incurred for items or services "where such expenses are for . . . hearing aids or examinations therefor. . . ."

The Medicare Benefit Policy Manual, Chapter 16, Section 100, states, " Hearing aids are amplifying devices that compensate for impaired hearing. Hearing aids include air conduction devices that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles."

The Manual additionally states that, " Certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery."

CMS has determined that cochlear implants are not subject to the hearing aid exclusion. See 42 C.F.R. § 411.15(d)(2)(ii).

Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

IV. Timeline of Recent Activities

Date	Actions Taken
March 1, 2022	CMS initiates this NCA. A 30-day public comment period begins.
March 31, 2022	First public comment period ends. CMS receives 35 comments.
July 6, 2022	Proposed Decision Memorandum posted. 30-day public comment period begins.
August 5, 2022	Second public comment period ends. CMS receives 151 public comments.

V. Food and Drug Administration (FDA) Status

The FDA has approved the cochlear implants of four companies. All four approved cochlear implant systems are indicated to restore auditory sensation via the electrical stimulation of the auditory nerve. Overall, a patient eligible for a cochlear implant has significant sensorineural hearing loss either bilaterally or in the ear to be implanted and obtains little to no benefit from appropriately fit hearing aids. The precise patient eligibility criteria of each cochlear implant system is based on audiological and speech recognition measures that may differ between manufacturers. At least one cochlear implant is FDA approved for patients with bilateral moderate-to-profound or severe-to-profound sensorineural hearing loss and tested to demonstrate ≤ 60% correct on open set sentence recognition tests in the best aided condition.

VI. General Methodological Principles

When making national coverage determinations, CMS generally evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit

category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for beneficiaries. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the Agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix A.

Public comments sometimes cite published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. Public comments that contain excessive personal health information that cannot be redacted will not be made available to the public. CMS responds in detail to the public comments on a proposed national coverage determination when issuing the final national coverage determination.

VII. Evidence

A. Introduction

This section provides a summary of the evidence we considered during our review. The evidence reviewed to date includes the published medical literature on pertinent clinical trials of cochlear implantation. Our search was originally for literature that provided information regarding adult study subjects with bilateral sensorineural hearing loss who demonstrated pre-cochlear implant sentence recognition scores between 41% and 60% and whose post-surgical sentence recognition outcomes were tracked for at least six months. However, some authors presented such information only in graphic form and it was impossible to distinguish patients whose pre-implant scores were on the borders of the expansion criteria (e.g. 40% versus 41% correct). Moreover, some authors compared the change in speech scores from pre to post cochlear implant in individuals with pre-implant scores of <40% versus 40% – 60% correct. Other authors may have included patients who received a cochlear implant but whose outcome was only tracked for three months. Not wishing to ignore this information, we expanded our search parameters to include studies providing information regarding adult subjects with bilateral sensorineural hearing loss who demonstrated pre-cochlear implant sentence recognition scores between 40% and 60% correct and whose post-surgical outcomes were reported in such a manner that individualized outcomes could be generally determined. The information regarding outcomes could be available in the form of text, tables or figures. Where necessary, attempts were made to contact authors in order to obtain the most precise information possible.

In lieu of investigations providing the diagnoses of their subjects, we assumed "bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss" if authors stated that the Medicare criteria for cochlear implantation were followed. However, if diagnoses were not listed or Medicare criteria were not discussed, or authors could not be contacted to provide this needed information, the article was excluded from our evaluation.

B. Discussion of Evidence

1. Evidence Question

The following question guided our review and analysis of the evidence below:

- Is the evidence sufficient to conclude that cochlear implantation may be reasonable and necessary for

treatment of adult Medicare beneficiaries with bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss who demonstrate limited benefit from amplification? Limited benefit from amplification is defined by pre-cochlear implant sentence recognition scores greater than 40% and less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence recognition.

2. External Technology Assessments

CMS did not request an external technology assessment (TA) on this issue.

3. Internal Technology Assessment

Literature Search Methods

The reviewed evidence was gathered from articles submitted by the requester, from a literature search of PubMed and Embase performed by CMS staff, from literature suggestions provided to us by external stakeholders during the first public comment period and from a hand search of pertinent review articles and clinical investigations. We searched for clinical investigations, systematic reviews and guidelines, using key words which included cochlear implant and cochlear implantation. All literature reviewed was examined to determine if it contained relevant information in text as well as diagrams, charts, graphs, etc.

Our literature search was not constrained by date. However only English language articles were evaluated for the information they contained. For each investigation that met our criteria for inclusion in this NCA, we attempted to summarize the general results of the study. However, if information outside the scope of this NCA was found in the assessed literature and was believed not to be pertinent to our evidence review, we did not further describe, nor discuss it below.

In order to augment the information found in their respective publications and allow us as much precision as possible, the following authors of the articles summarized in our Evidence Section provided information regarding patient diagnoses and speech recognition scores that was not contained in their journal manuscripts. We are most grateful to these individuals for their cooperation with this NCA as well as the time and effort they have expended on behalf of the Medicare beneficiary population. All provided information was de-identified.

- Daniel H. Coelho, M.D., F.A.C.S., G. Douglas Hayden Professor Otologic & Neurotologic Surgery, Departments of Otolaryngology – Head & Neck Surgery, Neurosurgery, Physiology & Biophysics, Virginia Commonwealth University School of Medicine, Richmond, Virginia
- Frank Lin, M.D., Ph.D. Director, Cochlear Center for Hearing and Public Health, Johns Hopkins Bloomberg School of Public Health; Professor of Otolaryngology - Head and Neck Surgery, Professor of Medicine, Johns Hopkins Medicine, Baltimore, Maryland
- Emily M. H. Lundberg, AuD, Postdoctoral Fellow, Department of Speech-Language-Hearing Sciences, University of Colorado at Boulder, Boulder, Colorado
- Abraham Jacob, M.D., Medical Director, Ear & Hearing, Center for Neurosciences, Tucson, Arizona
- Ted McRackan, MD, MSCR, Director, Skull Base Center, Medical Director, Cochlear Implant Program, Associate Professor, Department of Otolaryngology - Head and Neck Surgery Medical University of South Carolina, Charleston, South Carolina
- Elizabeth Perkins, M.D. Otology/Neurotology, Assistant Professor of Otolaryngology/Head and Neck Surgery, Director of Pediatric Neurotology, Vanderbilt University Medical Center, Nashville, Tennessee
- Darcy Strong, AuD, Clinical Audiologist, Department of Speech-Language-Hearing Sciences, University of Colorado at Boulder, Boulder, Colorado
- Sharon Miller, Ph.D., CCC-A, Department of Audiology & Speech-Language Pathology, University of North Texas

We would also like to recognize the contributions of the late John Niparko, M.D. to this National Coverage Determination.

We found nine clinical investigations that met our inclusion criteria. We also reviewed an expert panel consensus statement and a professional society guideline. The details of this literature are summarized below.

Dornhoffer JR, Reddy P, Meyer TA, Schvartz-Leyzac KC, Dubno JR, McRackan TR. Individual Differences in Speech Recognition Changes After Cochlear Implantation. JAMA Otolaryngol Head Neck Surg. 2021 Mar 1;147(3):280-286. doi: 10.1001/jamaoto.2020.5094. PMID: 33410869; PMCID: PMC7791403.

This cross-sectional study assessed changes in pre-operative aided vs post-operative speech recognition scores for individual patients receiving cochlear implants when considering the measurement error for speech recognition tests. Data was collected from a prospectively maintained database of patients who received cochlear implants between January 1, 2012, and December 31, 2017, at a tertiary, university-based referral center. Adults with bilateral sensorineural hearing loss undergoing cochlear implantation with six- or twelve-month post-operative measures using one or more speech recognition tests were studied. Inclusion criteria were documented history of post-lingual onset of hearing loss, age of 18 years or older at the time of implantation, and pre-operative aided and 6-month or greater post-operative speech recognition scores. Exclusion criteria were revision and implantation for single-sided deafness.

Data was available from 323 patients with 470 implants. Mean duration of hearing loss (self- reported) for the entire group prior to device implantation was 24.3 (SD 17.3) years and mean age at implantation was 61.2 years (SD = 18.3) Active hearing aid use (self-reported) was reported by 282 patients pre-operatively. For 147 patients undergoing bilateral cochlear implantation, each ear was treated as an independent outcome.

The database provided speech recognition scores for the 470 implants measured separately for each ear in the best aided condition before implantation and with their cochlear implant 6 months (26.8%) or 12 months (73.2%) after implant activation. Speech recognition scores were obtained with AzBio sentences in quiet (AzBio Quiet) and AzBio sentences in noise at a +10-dB signal-to-noise ratio (AzBio +10). Noise was a multitalker babble. AzBio +10 was only administered to patients whose AzBio Quiet scores were 50% or greater.

Pre-operative speech recognition was measured in the sound field with hearing aids (personal or clinic stock aids) fitted to revised National Acoustic Laboratories targets. All speech recognition testing was performed with speech presented at 60-dB sound pressure level (0° azimuth for speech and if pertinent, noise). Complete aided and cochlear implant sentence recognition scores in quiet were available in 258 patients and in noise, in 42 patients. All pre-operative to post-operative speech recognition score comparisons were made within the same ear. The mean percentage improvement in available AzBio Quiet scores (post-operative score minus pre-operative score) 6 or 12 months after implantation was 45.6% (d = 2.09; 95% CI, 1.92-2.26) and 33.6% for AzBio +10 (d = 1.79; 95% CI, 1.63-1.95).

Pertinent data was displayed in a scatterplot that compared pre-operative aided speech recognition scores with post-operative scores in the same ear. Each data point was compared to published 95% CIs for the speech recognition test given. Patients who had improvements in their speech recognition scores above the upper 95% CI limit of that measure were considered to have statistically significant improvement. Those who had changes in their score within the two 95% CI limits were considered to have no significant change, and those who had changes in their score below the lower 95% CI limit were considered to have significant decline.

Figures in the text as well as personal communication with the corresponding author were the sources of information regarding the information below.

Nine individuals in the study exhibited pre-operative AzBio scores between 40 and 60% (seven exhibited scoring between 41% and 60%). Post-operatively three of those individuals exhibited significant improvement in their sentence recognition scores in quiet within the same ear and six exhibited no significant change. None of the patients with pre-operative sentence recognition scores between 40% and 60% demonstrated significant decline in their sentence recognition (in quiet) scores. Those patients who demonstrated significant improvement post-

operatively exhibited initial sentence recognition scores of 40%, 40% and 45% and post-operative scores of 71%, 72% and 91% respectively. Of those individuals who demonstrated no significant change, the pre-cochlear implant scores ranged from 48% to 56% and the post-operative scores for five out of six subjects changed between 2% and 15%. One patient demonstrated a loss of sentence recognition (-13%).

Moreover, two individuals exhibited a pre-operative AzBio +10 score between 40% and 60%. One of those individuals exhibited significant improvement in their sentence recognition in noise scores with a score change from 57% pre-operatively to 85% post-operatively, and one patient exhibited no significant change in sentence recognition score (pre-op 40%; post-op 49%).

Table 1

AzBio Quiet		
Patient	Pre	Post
A	40	71
B	40	72
C	45	91
D	48	50
E	49	62
F	52	67
G	53	40
H	55	62
I	56	58
AzBio +10 SNR		
J	40	49
K	57	85

The authors noted that though most patients in their study (those whose pre-operative scores are both greater than and less than 40%) had significant improvement in sentence recognition tests post-operatively overall, the information needed to predict post implantation outcomes for individual patients is not yet available. There may be large variability in what potential cochlear implant candidates may expect based on their pre-operative aided scores. The authors stated presenting individual patient data from a large sample of cochlear implant users provides a better

understanding of individual differences in speech recognition outcomes and contributes to more complete interpretations of successful outcomes after cochlear implantation.

Dunn C, Miller SE, Schafer EC, Silva C, Gifford RH, Grisel JJ. Benefits of a Hearing Registry: Cochlear Implant Candidacy in Quiet Versus Noise in 1,611 Patients. Am J Audiol. 2020;29(4):851-861. doi:10.1044/2020_AJA-20-00055.

Among the goals of this retrospective study was to examine the post-operative sentence recognition outcomes in patients who qualify for a cochlear implant based on speech scores in quiet or noise. The clinical data was derived from a national, multicenter cochlear implant database from 12 clinical sites across the nine states of Colorado, Iowa, Maryland, New York, Ohio, Oklahoma, Tennessee, Texas and Wisconsin. The patients in the database represented both cochlear implant candidates and/or recipients ranging in age from 0 to 102 years who received implants from 1978 to 2019. Of those in the database (n= 7275), 6,599 unique implantations were queried to include only those cases with pre-operative AzBio sentence recognition scores (n=2979). After excluding bilateral recipients, the data set was narrowed to include only those with an AzBio sentence recognition score ≤ 40% in the best-aided condition in quiet or noise. The best-aided condition was defined as the listening condition with the highest score whether this represented the aided score of the ear to be implanted or the bilateral hearing aid score. Implantation dates ranged from 2008 to 2019. These final 1,611 patients were divided into three implant qualifying groups based on the test condition that resulted in ≤ 40% correct for AzBio sentences. Groups included those who qualified in quiet (N = 1,020), at a +10 signal-to-noise ratio (SNR; n = 155), or at a +5 dB SNR (n = 436). Presentation levels ranged from 48 to 65 dB SPL in greater than 99% of tests. Most patients had scores in more than one test condition (e.g., +10 dB SNR and in quiet), but patient data were assigned to the least adverse listening condition in which they scored ≤40% correct. The three qualifying groups of CI candidates were refined to include patients with at least one pre-operative AzBio score and one best post-operative AzBio score in the same listening condition (quiet, +10 dB SNR, +5 dB SNR) collected between 3 and 24 months post activation.

For all CI qualifying groups, mean post-operative speech recognition performance significantly improved in quiet. In the quiet listening condition, those who qualified in quiet experienced an average improvement of 52% points compared to the +10 dB SNR or +5 dB SNR qualifying groups who experienced 14% and12% point improvements, respectively. Patients in all three qualifying groups also experienced significant post-operative improvement in noise. However, patients who qualified in noise experienced greater post-operative benefit in noise than in quiet. For example, the +10 dB SNR qualifying group experienced an average improvement of 35% when post-operative testing was performed in the same +10 dB SNR condition compared to a 14% improvement in quiet and 32% improvement in a +5 dB SNR condition. The +5 dB SNR qualifying group experienced a 32% improvement in the same post-operative +5 dB SNR condition compared to the +10 dB SNR (15% improvement) or quiet (12% improvement) conditions. When tested in the most difficult noise condition (+5 dB SNR), patients in the quiet qualifying group obtained similar average post-operative improvement as observed for the two noise qualifying groups.

More specifically, per information from the author and figures in the article, of those patients who qualified in noise (+10 dB SNR or +5dB SNR) for cochlear implantation and who pre-operatively in demonstrated AzBio scores between 41% and 60% (111 patients), the majority exhibited significantly higher post-operative scores when tested in quiet. Approximately seven patients lost critical hearing in quiet and approximately 20 patients experience no significant change post-operatively. Of those individuals who qualified in noise (+5dB SNR) and who pre-operatively demonstrated AzBio scores between 41% and 60% at +10 dB SNR (12 patients), seven demonstrated significant improvement in hearing post-operatively (+ 10db SNR), while one showed a decrement and four exhibited no significant change.

The authors concluded that approximately one third of adult cochlear recipients would qualify in noise based on Medicare policy. Though across the entire spectrum of these three qualifying groups there was a significant improvement between the pre-operative and post-operative scores, individual cochlear implant patients derived the greatest post-operative speech perception benefit in their qualifying condition. Furthermore, the authors noted that if patients who qualified in noise were only tested post-operatively in quiet, not all would show significant

improvement with their implant. Patients should be counseled pre-operatively that expectations of post-operative improvement differ based on their qualifying test condition.

Lin FR, Chien WW, Li L, Clarrett DM, Niparko JK, Francis HW. Cochlear implantation in older adults. Medicine (Baltimore). 2012; 91(5):229-241. doi:10.1097/MD.0b013e31826b145a. PMID: 22932787.

This analysis of clinical database information reviewed 12 years of experience with cochlear implantation in older adults at Johns Hopkins focusing on the impact of the cochlear implant on speech understanding and identifying factors that are associated with speech outcomes. Eligible study subjects were individuals 60 years old or greater, receiving a first cochlear implant at the Johns Hopkins Listening Center from 1999 to June 2011 (n = 445). Nearly 60% of these implantations were performed in adults over 70 years with the oldest recipient being almost 95 years at implantation. Over three-quarters of these older adult CI recipients experienced hearing loss that developed in later life rather than being of congenital or early onset.

The data from a subset of patients who had Hearing in Noise Test (HINT) speech tests available both pre-operatively and approximately one-year post-cochlear implant activation (range 9–14 months) were analyzed. Additionally, one subject had post cochlear implant speech data assessed at 21 months after device activation because of a delay in cochlear implant programming related to vestibular schwannoma surgery.

Data were manually filtered to select patients in whom the HINT scores were obtained under as similar conditions as possible. (HINT sentence testing was comprised of a list of 20 recorded sentences that were presented to the patient in quiet in a sound booth. The patient's speech score was calculated as the percent of words repeated back correctly.) Out of a total of 445 patients who received a first cochlear implant during the designated time span, 83 patients were found to have HINT testing scores that were retained in the database and were always presented at identical presentation levels (e. g. 60dB) both pre and post-operatively. Per the author, 17 patients with baseline sentence recognition scores between 40% and 60% were included in this group. Fourteen of these 17 patients were diagnosed with bilateral progressive sensorineural hearing loss. The diagnosis of three patients is unknown.

Patients were always tested under binaural best-aided conditions pre-operatively, and post-implant HINT speech scores were generally done under cochlear implant only conditions with the exception of 9 individuals who were tested at one year under binaural best aided conditions.

All 83 patients were noted to have improved speech scores one year after cochlear implantation with mean pre-cochlear implant HINT speech scores of 19.8% (SD 2.0) improving to 79.8% (SD 2.1) after implantation ($p < 0.001$). Further, the authors also investigated the association of pre-implantation speech scores with post-operative outcomes by analyzing the change in HINT speech scores from pre to post cochlear implant in individuals with pre-implant HINT speech scores of <40% (mean 12.8 [SD 12.9]) versus 40– 60% (mean 47.5 [SD 6.5]). While the magnitude of the change in HINT speech scores was greater in individuals with pre-implant scores of <40% (mean change 64.6 [SD 24.5] vs. 42.2 [SD 10.6]), speech scores at one-year post- implantation were on average higher in those individuals with greater pre-implantation speech scores (post cochlear implant speech score of 89.7% [SD 2.2] vs. 77.3% [SD 2.5] in individuals with pre-implant speech of 40–60% vs. <40%, respectively [$p<0.001$]). The observation of pre-cochlear implant speech scores between 40–60% being associated with higher post-implant speech scores persisted after adjustment for age at time of cochlear implantation and age of hearing loss onset in regression models. On average, individuals with pre-implant speech scores of 40–60% had post-implant HINT speech scores 10.0 percentage points (95% CI: 0. 4– 19.6, $p =0.4$) higher than individuals with pre-CI speech scores <40% after adjusting for age at implantation and age at hearing loss onset. Of the individuals with HINT scores of 40 – 60% prior to cochlear implantation, almost all achieved a post-implant score of greater than 80% and none of the individuals in this group exhibited a decline in their HINT scores one-year post surgery.

Based on the above, the authors concluded that delaying cochlear implantation in older adults (restricting cochlear implantation to only individuals with pre-operative speech scores <40%) may prevent some patients from using the cochlear implant to its fullest potential. Allowing for cochlear implants in adults with pre-operative speech scores between 40 and 60% may allow patients to derive greater benefit from these devices and lead to greater quality of life gains for the individuals who use them.

Lundberg EMH, Strong D, Anderson M, Kaizer AM, Gubbels S. Do Patients Benefit From a Cochlear Implant When They Qualify Only in the Presence of Background Noise? Otol Neurotol. 2021;42(2):251-259. Doi:10.1097/MAO.0000000000002878.

The purpose of this investigation was to compare the difference in pre- to post-operative speech performance of patients qualifying for a cochlear implant in quiet, +10 dB signal-to-noise ratio (SNR), and +5 dB SNR. A retrospective review of the medical record was completed for 58 consecutive individuals (mean age: 72.26 years, SD: 14.39 years; age range: 20.46-90.63 years) who received their first cochlear implant at a tertiary care center cochlear implant program between June 2015 and December 2017. All included patients were post-lingually deafened, unilateral cochlear implant users with bilateral sensorineural hearing loss, who underwent AzBio sentence recognition testing pre-operatively and post-operatively. Patients in this study were required to have a pre-operative AzBio score and at least one post-operative score obtained between 10 and 14 months post cochlear implant activation to be included. Individuals who received a contralateral CI within 12 months of the first surgery, received reimplantation for revision surgery for any reason, had a known retro-cochlear abnormality, or had no audiometric assessment test results between 10 and 14 months post-activation were excluded.

Sentence recognition testing was performed in quiet using AzBio sentence lists for each ear aided individually and bilaterally aided, and in noise using AzBio sentence lists tested at both +10 and + 5 dB SNR for each ear aided individually and aided bilaterally. All testing was performed at zero degree azimuth, with speech and noise co-located. Post-operatively, for patients with aidable hearing (determined by thresholds, speech recognition performance using the hearing aid, and patient subjective determination) in the nonimplanted ear, AzBio testing was performed in the bimodal (CI+ contralateral HA) in addition to the CI alone condition.

Medicare patients who were candidates for cochlear implantation in this study exhibited recorded sentence recognition scores less than or equal to 40% correct in the best-aided condition. However, patients with private insurance who were candidates for cochlear implantation exhibited sentence scores less than or equal to 50% in the ear to be implanted and less than or equal to 60% in the opposite ear or binaurally. Patients meeting these criteria were divided into three groups based on their qualifying test condition: sentence in quiet qualifiers (Group 1, n= 12), sentence in noise at +10 dB SNR qualifiers (Group 2, n = 16), and sentence in noise at + 5 dB SNR qualifiers (Group 3, n = 30). (Patients in Group 1 also met criteria in both noise conditions. Patients in Group 2 also qualified in the +5 dB SNR condition but not in quiet. Patients in Group 3 qualified in the + 5 dB SNR conditions but not in the +10 dB SNR nor in quiet conditions.)

For all patients in Group 2, post-operative AzBio sentence recognition with the cochlear implant alone compared with pre-operative scores of the implant ear alone improved in quiet by 52.2 percentage points [95% CI: (36.0, 68.3), p< 0.001]. On average, post-operative AzBio sentence recognition in the best-aided condition in quiet improved by 12.5 percentage points, though this improvement was not significant [95% CI: (-11.5, 36.5), p = 0.238]. AzBio sentence recognition in the best-aided condition in noise at + 10 dB SNR improved by 30.9 percentage points [95% CI: (12.4, 49.3), p = 0.005] and improved at +5 dB SNR by 22.5 percentage points [95% CI: (1.0, 44.0), p = 0.043].

Specific to the question posed in this NCA, the following information was provided by the author. There were 10 individuals who qualified for a cochlear implant in Group 2 (+10 Qualifiers) and who exhibited a pre-op AzBio score in the cochlear implant ear in quiet between 41% and 60%. Of these individuals, seven experienced an improvement in the implanted ear alone in quiet and one experienced a decrement (pre-operative score was 50% and post-operative score was 47%). Two individuals were not tested post-operatively in quiet.

Additionally, there were four +10 Qualifiers with pre-op AzBio scores in quiet between 41% and 60% whose post-operative best aided in quiet score was recorded. Of the four, three improved post-operatively and one experienced a decrement (58% pre-op to 51% post-op). One of the three individuals who improved in their best aided quiet score was the individual with the decrement in the paragraph above.

Of the five +10 Qualifiers with a pre-op AzBio score between 41% and 60% tested in the best aided condition at +10dB SNR, all improved in that noise level post-operatively.

Of all the Group 3 qualifiers, AzBio sentence recognition with the cochlear implant alone compared with pre-operative scores of the implant ear alone improved in quiet by 28.7 percentage points [95% CI: (10.3, 47.1), p<0.001]. Though improvement in the best-aided condition in quiet trended positively by 2.8 percentage points [95% CI:(-8.0, 13.5), p= 0.563], this improvement was not significant. Improvement in AzBio sentence recognition in the best-aided condition in noise at + 10 dB SNR and + 5 dB SNR however, was significant, increasing by 16.1 percentage points [95% CI:(4.2, 28.0), p = 0.012] and 14.1 percentage points [95% CI:(5.0, 23.1), p=0.005] respectively.

The author also provided the below information regarding the three of 58 patients in this study who qualified for cochlear implants with AzBio scores between 41% and 60% in +5 dB SNR noise:

Table 2

Patient	Pre-operative AzBio score in quiet best - aided	Pre-operative AzBio score in noise (+10 dB SNR) best aided	Pre-operative AzBio score in noise (+5 dB SNR) best aided	Post-operative AzBio score, in quiet bimodal	Post-operative AzBio score bimodal in noise (+10 dB SNR)	Post-operative AzBio bimodal score in noise (+5 dB SNR)
A	95%	64%	51%	Not tested	Not tested	83%
B	94%	78%	42%	82%	61%	Not tested
C	97%	77%	60%	100%	92%	72%

The authors based their conclusions on all the patients studied in this investigation. They state that it is important to consider the status of the non-implanted ear, as well as the plan of treatment for that ear when making candidacy decisions. The overall evidence of the current study suggests that for individuals with higher pre-operative scores (e.g., individuals qualifying at 5 dB SNR but not at 10 dB SNR), post-operative objective outcomes can be variable. It is important to assess individuals for cochlear implant candidacy as well as track their post-operative course with materials that are ecologically valid. Studies classifying real-world SNRs based on recordings of everyday listening situations of hearing aid users with an average pure tone average between 25 and 60 dB HL have found that for speech in babble noise, the median SNR was slightly below 5 dB. Based on this information, the authors believe it would be logical to test potential candidates for cochlear implantation at 5 dB. However, the authors also emphasize that if cochlear implant candidates are avoiding environments with low SNRs or are not practicing listening in noise, this may be an unrealistic test condition. If an individual only qualifies for a cochlear implant in noise, but does not find themselves in noisy environments in their everyday life, a cochlear implant may not be a good solution given the risk of speech recognition in quiet declining post-operatively. While individuals qualifying for a cochlear implant only in the +5 dB SNR condition may derive significant benefit from implantation, speech understanding outcomes can be more variable for this group. As such, the status of the contralateral ear as well as daily listening needs should be considered in candidacy and pre-operative counseling and caution should be strongly emphasized in this population before implantation.

Mudery JA, Francis R, McCrary H, Jacob A. Older Individuals Meeting Medicare Cochlear Implant Candidacy Criteria in Noise but Not in Quiet: Are These Patients Improved by Surgery? Otol Neurotol. 2017;38(2):187-191. doi:10.1097/MAO.0000000000001271.

The purpose of this study was to determine whether older patients meeting Medicare's cochlear implantation NCD criteria in noise, but not in quiet, are objectively improved after implantation, both in quiet and in noise. The authors retrospectively reviewed candidacy and outcomes data for 136 cochlear implantation surgeries performed between January 2013 and September 2015 in patients with bilateral sensorineural hearing loss.

In the aided condition, sentence recognition tests were performed using AzBio sentence scoring. Results were measured for monaural conditions (right hearing aid only, left hearing aid only) and the bilateral condition. If the patient performed greater than 40% in quiet in the best aided condition, further testing was conducted in the presence of noise. For in noise testing, AzBio sentence recognition scores were determined in the presence of competing multi-talker babble with an initial signal–noise ratio (SNR) of +10 dB. If the patient performed greater

than 40% in this best-aided condition, further testing was conducted using a SNR of +5 dB. Noise was presented at the 0 or 180 degrees azimuth, but remained consistent for each individual during their follow up visits.

For all patients in the study (n=15), pre-operative AzBio scores for the implanted ear averaged 47% in quiet and 9% in noise at +10 or +5 dB SNR. Pre-operative bilateral condition AzBio scores averaged 70% in quiet and 24% in noise at +10 or +5 dB SNR. Patient follow-up in this group averaged 9 months, and overall post-operative results found that patients' hearing improved for every test condition. Post-operative AzBio scores for the implanted ear improved an average of 24% in quiet and 41% in noise. Bilateral testing revealed that AzBio scores improved 12% in quiet and 42% in noise. Paired t test analysis found that improvements in AzBio scores were statistically significant for the implanted ear in quiet, the implanted ear in noise, and the bilateral condition in quiet, and the bilateral condition in noise (p=0.001, 0.0003, 0.05, and 0.003, respectively).

Ten patients demonstrated AzBio pre-operative scores in quiet between 41% and 60%, either in the aided implanted ear and/or aided bilateral condition. AzBio scores for the best aided condition of the implanted ear alone and the bilateral hearing condition in quiet and noise are shown below. Post-operative values were measured at least six months after surgery.

Table 3

Patient	Age (years)	SNR (dB)	Implanted Ear AzBio (quiet) score (pre-op/post-op)	Bilateral AzBio (quiet) score (pre-op/post-op)	Implanted Ear AzBio (noise) score (pre-op/post-op)	Bilateral AzBio (noise) score (pre-op/post-op)
2	91	+10	51/82	58/57	-/-	-/-
3	80	+5	42/59	84/90	0/23	7/70
4	59	+10	26/67	49/99	9/72	-/-
5	65	+10	59/73	97/76	22/64	83/68
7	77	+5	55/73	72/95	1/59	2/94
11	66	+5	60/85	70/91	16/45	20/56
12	89	+10	41/45	72/77	15/3	27/30
13	85	+10	42/88	58/77	0/85	5/74
14	70	-	46/58	-/-	-/-	-/-
15	72	+5	45/50	29/63	3/19	11/45

Most of the above patients demonstrated improved hearing post-operatively in both quiet and noise. But though Subject #5 improved hearing in the implanted ear, in the bilateral condition hearing declined in quiet after cochlear implantation. Though the patient's hearing in noise also improved in the implanted ear post-operatively, hearing declined in noise in the bilateral condition after implantation.

Subject #12 as shown above, had no change in performance pre-to-post-operatively for hearing in quiet in the implanted ear or in the bilateral condition. But this patient demonstrated worsened hearing in noise for the implanted ear, though there was no decrement in noise bilaterally.

The authors noted that satisfaction with hearing aid use, particularly in background noise, can be poor in many elderly patients who may then look for alternative methods to improve their hearing. Their data suggested that when such patients are evaluated for cochlear implantation, if tested only in quiet and using Medicare criteria, their potential for improved hearing may not be recognized. The authors further stated that the typical signal-to noise ratio experienced for everyday listening is approximately +5 dB. Therefore, assessing speech understanding in noise for every patient may aid to reproduce real world situations. They believe cochlear implantation in those individuals who qualify in noise but not in quiet may significantly improve hearing in both conditions. However, the authors also note that though cochlear implantation in the majority of patients that they tested yielded improved hearing in quiet and noise, all patients were not improved, thereby making counseling an important part of the cochlear evaluation.

Perkins E, Dietrich MS, Manzoor N, et al. Further Evidence for the Expansion of Adult Cochlear Implant Candidacy Criteria. Otol Neurotol. 2021;42(6):815-823. doi:10.1097/MAO.0000000000003068.

The goal of this retrospective chart review investigation was to describe the post-operative performance trajectory for individuals who prior to cochlear implantation, demonstrated high performance characteristics. Included were all patients of a tertiary medical center greater than 16 years of age who underwent cochlear implantation from January 2009 to March 2019. Subjects with postlingual onset of deafness (sensorineural hearing loss) and who were native English speaking, with pre-operative CNC scores of greater than or equal to 30% correct in the ear to be implanted and up to 6- or 12-months listening experience were identified. Exclusion criteria included revision surgery, and lack of post-operative follow up.

For this study of 104 individuals total (105 ears), pre- and post-operative AzBio sentences in quiet and noise (+5 dB SNR) in the ear to be implanted and the bilateral-aided condition were tested before surgery and post-cochlear activation. All testing was completed with recorded stimuli at 60 dB SPL presented via a single loud speaker at 0-degree azimuth placed at a distance of 1 m from the listener. Sentences were presented in quiet and in 10-talker babble at +5 dB SNR. Pre-operatively, all patients were tested with each hearing aid alone as well as with bilateral hearing aids. Post-operatively, all patients were tested with the unilateral cochlear implant only (nonimplanted ear occluded with a plug) as well as the bimodal (cochlear implant with contralateral hearing aid; n=103) or bilateral cochlear implant (n=1) condition. Because clinical time was not unlimited, not all patients were tested with AzBio sentence recognition. The median age of implantation was 68 years (IQR 56, 76).

For all patients for whom scores were available (65 of 88 patients for the cochlear implanted ear alone; 57 of 80 for the bilateral condition), statistically significant improvements in AzBio sentences in quiet were observed from pre-operative to 12-months post-operative for both the CI ear and the bilateral listening condition. The median pre-operative score was 49% for the CI ear (IQR = 36, 65), with an improvement to median 76% (IQR= 59, 90) at 12-months post-operatively. Similar magnitudes of change were observed for the bilateral listening condition from a median 54% (IQR=42, 64) pre-operative to 91% (IQR = 80, 97) at 12 months. AzBio sentences in noise (+5 dB SNR) also demonstrated statistically significant improvements from preoperative to 12-months postoperative for both CI ear and bilateral listening conditions. The median preoperative score was 13% for the CI ear (IQR = 0, 22), with an improvement to median 31 % (IQR= 13, 54) at 12-months postoperatively. Similar magnitudes of change were observed for the bilateral listening condition from a preoperative median of 33% (IQR = 17, 47) to 66% (IQR = 43, 79) postoperatively at 12 months. (Twelve-month data were available for 33 of 45 patients for the Cl-alone condition and 43 of 56 patients for the bilateral condition.)

From the figures presented in the article, the majority of patients with pre-operative AzBio scores between 40% and

60% in quiet in the cochlear implanted ear with 12 month follow up data (approximately 21 patients), improved post-operatively. It appeared that three patients tested within the range of expected test-retest reliability and no one experienced a significant decrement in scores. Similarly, for the bilaterally aided condition in quiet, the patients with pre-operative AzBio scores between 40% and 60% with 12 month followup (approximately 8 patients), all appeared to improve their scores.

Furthermore, from the figures presented in the article, only two patients with pre-operative AzBio scores between 40% and 60% in noise in the cochlear implanted ear with 12 month followup are noted; one improved significantly and the other did not experience a significant decrement. For the bilaterally aided condition in noise, approximately 11 patients demonstrated pre-operative AzBio scores between 40% and 60%. Of these, it appears as if five demonstrated significant improvement in their scores at 12 months and only one patient showed a significant decrement.

The authors' conclusions were based mostly on the entirety of the investigation which predominantly involved CNC word testing for the assessment of cochlear implantation candidacy and are not pertinent to this NCA discussion. However, based on their results, the authors did state that statistically significant improvement was demonstrated for AzBio sentences in quiet and noise for the cochlear implant alone and bilateral listening conditions under the conditions of this study.

Thai A, Tran E, Swanson A, et al. Outcomes in Patients Meeting Cochlear Implant Criteria in Noise but Not in Quiet. Otol Neurotol. 2022;43(1):56-63. doi:10.1097/MAO.0000000000003351.

The goal of this study was to evaluate outcomes in patients qualifying for CI in noise but not quiet, with a focus on within-subject improvement beyond the test-retest variability of speech perception scores. A retrospective medical record review was conducted of patients receiving their first cochlear implant at a tertiary otology/neurotology clinic between 2012 and 2020. Only patients undergoing CI with available preimplant AzBio scores (in quiet or + 10 SNR) were included. Patients with device failure were excluded.

AzBio scores were recorded in the best-aided condition, consistent with CMS guidelines. Ears with preimplant AzBio quiet scores less than 40% were categorized into the quiet group (n=189). Ears with preimplant AzBio quiet more than or equal to 40% and preimplant AzBio +10 SNR less than or equal to 40% were categorized into the noise group (n=23).

The authors note that the test-retest variability of AzBio sentence lists has been reported, with a 95% confidence interval of 15 percentage points at its widest margin. Based on these results, within-subject improvement for AzBio quiet and + 10 SNR was defined as more than or equal to a 15-percentage point increase.

From examining the figures in the article, it appears that approximately eight patients in the noise group exhibited pre-operative AzBio scores in quiet between 40 and 60%. None of these patients experienced worsened scores post-operatively, however three patients did not experience a sentence score improvement equal to or greater than a 15-percentage point increase. It also appears from the figures in the article that potentially one patient in the noise group exhibited a pre-operative AzBio +10 SNR score between 40% and 60%; this subject was without significant improvement or decrement post-operatively.

Based on all the patients included in this study, the authors concluded that cochlear implant patients qualifying in noise display significant mean benefit in speech recognition scores but are less likely to improve compared with those qualifying in quiet.

Zhang E, Coelho DH. Beyond Sentence Recognition in Quiet for Older Adults: Implications for Cochlear Implant Candidacy. Otol Neurotol. 2018;39(8):979-986. doi:10.1097/MAO.0000000000001885.

The goal of this retrospective investigation was to study post-operative hearing outcomes in older adult cochlear implant recipients who did not meet Medicare candidacy criteria in quiet. Medical records were examined and fifty-four individuals, aged 60 years of age or greater, with bilateral moderate to profound sensorineural hearing loss who underwent unilateral cochlear implantation between January 2011 and November 2016 were included. Sentence

recognition was assessed using the AzBio test. All testing was done in the bilateral best-aided condition using either personal or loaner hearing aids set to National Acoustic Laboratories prescriptive targets within 5 dB. If patients scored better than 40% correct, a second AzBio test was administered in noise (multitalker babble, +5 dB signal-to-noise ratio). All post-operative data used in the study was collected at least 6 months after activation, with a majority of post-operative data collected after at least 1 year of implant usage. Testing was typically performed in the implanted ear and in bilateral ears in both quiet and noise, but testing combinations varied based on audiologist preference and patient ability. Post-operatively, AzBio sentences in quiet in the best-aided condition were analyzed, though noise testing may also have been included in the patient assessment.

The author provided the specific data below. Three of the 54 patients included in this study exhibited pre-operative AzBio scores in quiet between 41% and 60% inclusive. Their results are below:

Table 4

Patient	Pre-op AzBio score (quiet)	Post-op AzBio score (quiet)	Pre-op AzBio score (in noise)	Post-op AzBio (in noise)	Follow up
1	60%	93%	31%	64%	1 year
2	60%	99%	34%	81%	1 year
3	60%	90%	6%	90%	6 months

The authors' conclusions were based on all participants of the study. They stated that this study found that patients who qualified by the addition of noise to their sentence testing condition experienced an average of 20% improvement in sentence understanding. The authors further stated that the most common motivation for cochlear implantation in an elderly patient is dissatisfaction with hearing aids. Moreover, while most hearing aid users have complaints in all listening conditions, many seek cochlear implantation based on particular difficulties in background noise and its effects on quality of life. Therefore, speech testing in noise is performed in many centers when evaluating patients for cochlear implant candidacy. The authors believed that testing in noise is a more accurate reflection of real-life conditions that is less likely to exclude potential beneficiaries. They stated that the results of this study demonstrate that older patients who do not meet current Medicare candidacy criteria derive significant long-term benefit from cochlear implantation when sentence recognition in noise is used to determine candidacy. They also emphasized that care must be taken to avoid implanting patients who will receive only marginal or even no benefit.

Zwolan TA, Kallogjeri D, Firszt JB, Buchman CA. Assessment of Cochlear Implants for Adult Medicare Beneficiaries Aged 65 Years or Older Who Meet Expanded Indications of Open-Set Sentence Recognition: A Multicenter Nonrandomized Clinical Trial. JAMA Otolaryngol Head Neck Surg. 2020 Oct 1;146(10):933-941. doi: 10.1001/jamaoto.2020.2286. PMID: 32857106.

The purpose of this multicentered, nonrandomized clinical trial was to examine the effectiveness of available multichannel cochlear implant systems, as measured by improvement on the AzBio Sentence Test, for newly implanted Medicare beneficiaries who meet the indications of a test score between 41% and 60% on a recorded hearing test of open set sentence recognition in their best-aided condition. (Test measures were selected based on the recommendations provided in the Minimum Speech Test Battery and their widespread use in clinical care with recipients of cochlear implants.) Additionally, the study assessed the relationship between measures of speech recognition in candidates for cochlear implants and quality-of-life post implantation.

Participants received a cochlear implant between September, 2014 and July, 2018. Each participant was 65 years or older and eligible for Medicare as their primary source of medical insurance. Each participant also demonstrated bilateral moderate to profound hearing loss in the low frequencies (≤ 1000 Hz) and profound sensorineural hearing loss in the high frequencies (≥ 3000 Hz), and had a pre-operative sentence score in quiet that was 41% to 60% correct when recorded sentences were presented in the best-aided condition. (In the original protocol for this investigation, the Hearing in Noise Test (HINT) sentences were used as the qualifying measure for participation in this trial. However, the authors noted that many centers ceased to use HINT sentences as a measurement of hearing loss and therefore the protocol was changed in July, 2015, in order to qualify participants with the AzBio Sentence Test.)

Exclusion criteria of the study were the onset of hearing loss prior to the age of 2 years, cochlear ossification, absence of cochlear development or any other cochlear anomaly that might prevent complete insertion of the electrode array, a hearing loss suspected to be of neural or central origin, an active middle ear infection, or a disabling cognitive limitation.

The primary outcome measure of the trial was the change in the AzBio Sentence Test score obtained post-operatively compared with the baseline score obtained prior to receiving the cochlear implant. A 25% improvement in the AzBio Sentence Test score was defined as the minimally clinically important difference in the best-aided condition, and an improvement of 30% was defined as the minimally clinically important difference in the implanted ear. Speech recognition tests were presented in a quiet setting in the sound field at a 60-dB sound pressure level. Pre-operatively, speech recognition measures were administered when the participant used an appropriately fit hearing aid on their left ear alone, their right ear alone, and on both ears. Post-operatively, the speech recognition measures were performed with all participants when they used the implanted ear alone. Participants who used a hearing aid in the non-implanted ear more than four hours each day, additionally performed all speech recognition tests in the bimodal condition.

In addition to AzBio sentence recognition testing, self-assessment questionnaires were administered pre-operatively and 6 and 12 months post-operatively and included the Abbreviated Profile of Hearing Aid Benefit (APHAB), the 36-item Short Form (SF-36), and the Health Utility Index Mark 3 (HUI-3).

A total of 34 subjects received cochlear implants. Of the 34 individuals implanted, 31 and 29 subjects respectively, were available for the six- and 12-month data collections. Median age was 73.6 years (range, 65.7-85.1). Median pre-operative AzBio Sentence Test scores for all participants were 53% (range, 26%-60%) for the best-aided condition and 24% (range, 0%-53%) for the cochlear implant–alone condition; median scores 12 months after implantation improved to 89% (range, 36%-100%) for the best-aided condition and 77% (range, 13%-100%) for the cochlear implant–alone condition.

Data was available for 31 subjects. Twelve participants had a baseline AzBio Sentence Test score of 50% or less (group 1), while 19 participants had a baseline score of 51% or more (group 2). [Three participants originally qualified on their HINT scores. Their pre-operative AzBio Sentence scores were 26%, 35% and 35%. These subjects were placed in group 1.] The authors stated that prior to cochlear implantation there were no significant differences between these two groups in terms of age at cochlear implant activation, sex, duration of hearing loss in the cochlear implant ear, duration of hearing loss in the contralateral ear, and duration of deafness in the cochlear implant ear.

Examination of individual scores revealed that 21 of 29 participants (72%) demonstrated an improvement in their AzBio Sentence Test score in the best-aided condition of more than 25% at 12 months. When examined by study group, all 12 of the group 1 participants and 9 of 17 of the group 2 participants (53%) experienced a change of more than 25% in their AzBio Sentence Test score in the best-aided condition at 12 months. Of the eight participants who improved less than 25%, four exhibited clinically important improvement (≥ 0.12) in the HUI-3 Multi. One participant in group 2 experienced a decline in speech perception scores; this participant was 81 years old and received a diagnosis of dementia after receiving the cochlear implant. The scores for the other seven subjects improved between approximately 5% and 20% .

Estimated marginal means (EMM), their differences, and the corresponding 95% CIs were used as measures of effect

size in the outcome measure scores. At both the six and12 month marks, the authors noted statistically significant and clinically important improvement in estimated marginal means for the entire group of participants as compared to baseline AzBio Sentences in both the cochlear implant alone and best aided conditions. EMM differences were 32.3% (95%CI, 23.7%-40.9%) at 6 months and 35.4% (95% CI, 28.2%-42.5%) at 12 months in the best aided condition; and 42.4% (95%CI, 30.6%-54.2%) at 6 months and 49.6% (95% CI, 39.2%-60.1%) at 12 months in the cochlear implant alone condition. Similar results of improvement were noted with other measures of hearing (City University of New York Sentences on the telephone in the cochlear implanted ear and Consonant Nucleus Consonant (CNC) Monosyllabic Word Test in both the cochlear implant ear alone and the best aided condition).

The authors concluded that the results of this study demonstrated that currently available multichannel cochlear implant systems provide improvements in communication for adult Medicare beneficiaries 65 years or older with qualifying sentence recognition scores between 41% and 60%. Moreover, it was stated that these improvements in speech recognition appeared to be related to positive changes on self-reported assessments of quality of life. Furthermore, even when older adults did not reach the a priori clinically important speech recognition goals, the authors stated their results demonstrate important improvements in quality of life that are independent of audiologic performance after cochlear implantation.

4. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

A MEDCAC meeting was not convened on this issue.

5. Evidence-Based Guidelines

American Academy of Audiology Task Force on Cochlear Implant Practices. Clinical Practice Guideline: Cochlear Implants. July, 2019. Accessed on 1/27/2021 at: https://www.audiology.org/wp-content/uploads/2021/05/CochlearImplantPracticeGuidelines.pdf

The goal of this document was to provide a set of statements, recommendations, and strategies for best practices related to the evaluation for, and management of, cochlear implants. Statements and recommendations in this document were formed by initially reviewing scientific evidence published in peer-reviewed and non-peer-reviewed journals, first using studies at the top of the hierarchy of study types (e.g. systematic reviews and meta-analyses of randomized controlled trials; randomized controlled trials). If definitive clinical studies that provided valid relevant information were identified, the search for published materials stopped. The search was extended to studies/reports of lower quality only if there were no higher quality studies. When direct evidence was not available, both indirect evidence and consensus practice were considered in making recommendations.

Along with other information offered by these guidelines, it is noted that outcomes achieved with a cochlear implant vary widely and are attributed to multiple factors. In regards to speech perception as it pertains to candidacy for cochlear implantation, the Guidelines recommended that testing should be performed in the sound field using recorded test materials at a presentation level of 60 dBA SPL to reduce variability. A test battery that is developmentally and linguistically appropriate should be used. When testing adults, the recommendations provided in the manual of the Minimum Speech Test Battery (MSTB) should be followed, though modifications to components of the outcomes assessment test battery (specifically speech-perception testing) may be necessary on a case by case basis. Speech perception testing should be performed with each ear aided separately, as well as binaurally, to determine the patient's best aided condition.

Furthermore, objective measures and performance on speech perception measures are not always indicative of a recipient's perception of their individual performance. Assessment of subjective ability (e.g. quality of life) and determination of need should be documented as part of the candidacy process. Along with audiological and medical evaluations, additional evaluations provide valuable information in the candidacy process (e.g. cognitive, educational, speech and language and psychological evaluations).

6. Professional Society Recommendations / Consensus Statements / Other Expert Opinion

Buchman CA, Gifford RH, Haynes DS, et al. Unilateral Cochlear Implants for Severe, Profound, or

Moderate Sloping to Profound Bilateral Sensorineural Hearing Loss: A Systematic Review and Consensus Statements. JAMA Otolaryngol Head Neck Surg. 2020 Oct 1;146(10):942-953. doi: 10.1001/jamaoto.2020.0998. PMID: 32857157.

An international group of clinical experts in the fields of otology, audiology, and hearing science, with extensive clinical and scientific experience of cochlear implantation, were brought together to form a Delphi consensus panel. The aim of the group was to use a modified Delphi method to develop a series of consensus statements regarding the use of unilateral cochlear implants to treat severe, profound, or moderate sloping to profound bilateral sensorineural hearing loss (SNHL) in adults. The panel, informed both by a systematic review (SR) of the literature and clinical expertise, consisted of 30 international specialists who voted on the consensus statements during the time period between July, 2018 and March, 2019. The Delphi consensus method included two rounds of email questionnaires and a face to-face meeting of panel members at round 3.

The following pertinent consensus statements were endorsed by the Panel:

a) Preferred aided speech recognition tests for cochlear implant candidacy in adults include monosyllabic word tests and sentence tests conducted in quiet and noise. Further standardization of speech recognition tests is needed to facilitate comparison of outcomes across studies and countries.
b) When possible, hearing preservation surgery can be beneficial in individuals with substantial residual hearing.
c) Cochlear implants significantly improve speech recognition in both quiet and moderate noise in adults with severe, profound, or moderate sloping to profound bilateral SNHL; these gains in speech recognition are likely to remain stable over time.
d) Cochlear implants significantly improve overall and hearing-specific QOL in adults with severe, profound, or moderate sloping to profound bilateral SNHL.
e) Adults who are eligible for cochlear implants should receive the implant as soon as possible to maximize post-implantation speech recognition.
f) Many factors impact cochlear implantation outcomes; further research is needed to understand the magnitude of the effects.

7. Public Comment

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination.

CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum. All comments that were submitted without personal health information may be viewed in their entirety by using the following link: https://www.cms.gov/medicare-coverage-database/view/ncacal-public-comments.aspx?ncaid=306.

Initial Comment Period: 3/1/2022-3/31/2022

During the 30-day comment period following the release of the tracking sheet, CMS received 35 comments. Of these 35 comments, 3 were not published on the CMS website due to excessive personal health information content; however, all comments were considered for the proposed decision. The majority of comments, 32 comments, supported the expansion of the cochlear implantation patient criteria. Two commenters did not support expansion and one commenter did not state a clear position regarding coverage.

Comments were provided by cochlear implant programs, cochlear implant recipients, medical device companies, an associate professor; with the majority of comments (13) provided by physicians and audiologists. Six comments did not specify their titles and/or organizations. Six comments were provided by national associations/professional societies/coalitions, including the American Cochlear Implant (ACI) Alliance, American Speech-Language-Hearing Association (ASHA), Academy of Doctors of Audiology (ADA), Ohio Academy of Audiology (OAA), a joint comment from American Academy of Audiology and American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS),

and the Independence through the Enhancement of Medicare and Medicaid (ITEM) Coalition.

Numerous commenters provided references for our deliberation of this NCA. We very much appreciate this information. All such references were assessed for inclusion in our evidence review.

Second Comment Period: 7/6/2022-8/5/2022

During the 30-day comment period following the release of the proposed NCD, CMS received 151 comments. Of these 151 comments, 4 were not published on the CMS website due to excessive personal health information content; however, all comments were considered for this final decision. The majority of the comments, 149 comments, supported the expansion of the cochlear implantation patient criteria, one commenter did not support the expansion and one commenter did not state a clear position regarding coverage.

The majority of comments (102) were provided by physicians and audiologists. Five comments were provided by national associations/organizations, including the American Academy of Audiology, American Cochlear Implant (ACI) Alliance, American Speech-Language-Hearing Association (ASHA), Ear Community, and the Ohio Academy of Audiology (OAA). Eighteen comments did not specify their titles and/or organizations. Thirteen comments were provided by academia. The remaining 13 comments were provided by healthcare professionals (8), medical device companies (3), a cochlear implant program, and a research think tank.

All references submitted with public comments that were not considered for the proposed decision have been reviewed and analyzed for this final NCD.

Coverage Criteria

Comment: The great majority of commenters supported expanding coverage for cochlear implantation by broadening the patient criteria in regards to hearing test scores as well as allowing coverage of cochlear implants for beneficiaries not meeting the coverage criteria, when performed in the context of FDA-approved category B investigational device exemption clinical trials as defined at 42 CFR 405.201 or as a routine cost in clinical trials under section 310.1 of the National Coverage Determinations Manual titled Routine Costs in Clinical Trials.

Response: We appreciate the supportive comments.

Comment: Several commenters requested that CMS allow national coverage of cochlear implantation to treat asymmetric hearing loss and single sided deafness. One commenter also requested the coverage criteria for cochlear implants no longer include the requirement that patients be free from lesions in the auditory nerve and acoustic area of the central nervous system.

Response: As noted in the tracking sheet initiating this NCA, our focus was to consider expansion of the coverage for cochlear implantation for beneficiaries with bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss. We did not review the body of evidence related to coverage of cochlear implantation for individuals with single-sided deafness or asymmetrical hearing loss. Nor did we review evidence regarding the requirement that patients be free from lesions in the auditory nerve and acoustic areas of the central nervous system. An individual can request an NCD on these separate topics by following the procedures at: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/howtorequestanNCD.

Comment: One commenter requested that the NCD allow bilateral cochlear implantation.

Response: The NCD does not prevent the coverage of cochlear implants bilaterally. The coverage of two cochlear implants, placed either simultaneously or sequentially, may be covered at the discretion of the local Medicare Administrative Contractor.

Patient Criteria

Comment: Two commenters requested that standardized criteria for the evaluation of the patient who is being considered for cochlear implantation be established and that a stakeholder taskforce review and modify these criteria

as needed.

Response: The global evaluation of the beneficiary with hearing loss is not addressed in this policy. As noted above, the purpose of this NCA was to consider expansion of the coverage for cochlear implantation for beneficiaries with bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss. We recognize the variation in assessment practices for the patient who presents for cochlear implantation and acknowledge that sentence recognition is one of the many characteristics that physicians and audiologists must evaluate in their patients who present for this procedure.

Comment: One commenter who supported the expansion, suggested that our proposed decision referred to beneficiaries who demonstrate limited benefit from amplification as measured through "word recognition testing."

Response: We appreciate the commenters support of our proposed expansion in coverage, but this final NCD determines limited amplification as measured through open set sentence recognition, not word recognition.

Comment: One commenter suggested that CMS broaden access to all necessary aspects of services required for the provision of cochlear implantation, including for example, access to specialists needed in the recovery/rehabilitation process, transportation to follow-up and rehabilitation appointments.

Response: Medicare may only provide coverage for items and services that are: 1) eligible for a defined Medicare benefit category, 2) reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Medicare covers post-operative aural rehabilitation services which includes cochlear implant mapping/programming services.

We agree that cochlear implant patients will often require other medical services that are not addressed in this NCD. We will cover items and services that fall within the existing Medicare benefit categories, that are not specifically excluded, and that would be reasonable and necessary to treat the patients medical condition.

Medicare Administrative Contractor Coverage Discretion

Comment: One commenter expressed concern that after an IDE study ends, Medicare beneficiaries no longer would have access to the device. The commenter would like the Medicare Administrative Contractors (MACs) to be allowed to cover cochlear implantations performed with an FDA-approved device, for a patient who otherwise does not meet the coverage criteria in this NCD, if in the judgment of the local MAC, such use is medically necessary.

Response: The national coverage under this NCD is limited to those beneficiaries who demonstrate the defined criteria of bilateral sensorineural hearing loss noted as described in subsection B of NCD 50.3 (see Appendix B.) Per statute, the MAC coverage decisions may not conflict with national policy, including NCDs. An NCD reconsideration would be necessary for any new coverage indications not included in this final NCD. For any CMS-approved IDE trial, we encourage investigators to work with CMS in advance of the study being completed and in advance of FDA approval. This can help investigators and stakeholders prepare their request for an NCD reconsideration.

Adverse Events

Comment: One commenter did not support the expansion, indicating that not all cochlear implantations are successful. One commenter supported the expansion but wanted CMS to require cochlear implant manufacturers to gather further information regarding which patients are at greatest risk of serious adverse events prior to expanding coverage.

Response: We agree that, like all surgeries, cochlear implantation is not 100% successful for every patient. Indeed, we have noted this point in the Background (Section II of this NCA.) The peer-reviewed literature, including Carlson, 2020, recognizes that while cochlear implantation is not successful for every patient, the rates of failures are low (Layfield et al, 2021) and complications are low (Benoiton, MacLachlan, Mustard, Jayawardana & Bird, 2022). Thus, we are covering cochlear implantation nationally for beneficiaries that meet the specific criteria established in

subsection B of NCD 50.3 (see Appendix B.) With respect to the commenter supporting additional research regarding patients who are at greatest risk, we do not agree that such research is necessary before we expand coverage. Still, we would encourage additional research that would describe the characteristics of individuals that most closely are associated with positive or negative outcomes for those who undergo cochlear implantation. Additionally, it is important that physicians counsel their patients regarding the contemporaneous harms and benefits that result from all types of surgeries and procedures, including cochlear implantation.

VIII. CMS Analysis

National coverage determinations are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act (§1869(f)(1)(B)) by Medicare (§1862(l) of the Act). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A) of the Act).

When making national coverage determinations, it is important to consider whether the evidence is relevant to the Medicare beneficiary population. In considering the generalizability of the results of the body of evidence to the Medicare population, it is necessary to consider at least the age, race and gender of the study participants.

Evidence Review Summary:

This section of the decision memorandum provides an analysis of the evidence we considered during our review. The evidence includes the published medical literature and guidelines pertaining to the candidacy requirements of cochlear implants.

For this analysis, CMS focused on the following question:

Is the evidence sufficient to conclude that cochlear implantation may be reasonable and necessary for treatment of adult Medicare beneficiaries with bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss who demonstrate limited benefit from amplification? Limited benefit from amplification is defined by pre-cochlear implant sentence recognition scores greater than 40% and less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence recognition.

In general, studies showed marked mean/median improvement in sentence recognition scores after cochlear implantation has occurred. But as emphasized by Dornhoffer et al. (2021), individual outcomes following cochlear implantation are subject to a large degree of variability. Therefore, where possible, when assessing the success or failure of cochlear implantation in the range of interest of this NCA, it is prudent to examine the outcomes of individual patients who have undergone the procedure.

The investigation by Zwolan et al. (2020) is the only prospective study to specifically examine the outcomes of cochlear implantation, as measured by improvement for newly implanted Medicare beneficiaries in their best aided condition, who scored between 41% and 60% on a test of open set sentence recognition. In this trial of 34 participants who received a cochlear implant, 29 individuals completed the 12-month post implantation assessment. Results of the study demonstrated the median pre-operative AzBio Sentence Test scores for the total cohort were 53% (range, 26%-60%) for the best-aided condition and 24% (range, 0%-53%) for the cochlear implant alone condition; median scores 12 months after implantation improved to 89% (range, 36%-100%) for the best-aided condition and 77% (range, 13%-100%) for the cochlear implant–alone condition. This outcome represents a median change in AzBio sentence recognition from baseline of 36% (range, –22% to 75%) for the best-aided condition (lower bound of 1-sided 95% CI, 31%) and a median change of 53% from baseline (range, –15% to 93%) for the cochlear implant alone condition (lower bound of 1-sided 95% CI, 45%).

Eight of the 29 patients in the Zwolan et al. (2020) study who completed the 12-month study, did not reach the *a*

priori goal of 25% improvement in sentence recognition in the best aided condition after cochlear implantation. All were in Group II, those patients whose pre-operative AzBio sentence recognition scores were between 51 and 60%. A single patient who lost sentence recognition capability at the 12-month mark was diagnosed with dementia after cochlear implantation. The scores for the other seven subjects improved between approximately 5% and 20%. But of these eight individuals who improved less than 25%, four exhibited clinically important improvement in their report of health status and quality of life. This finding is in agreement with those who have noted that self-reported quality of life after cochlear implant can be independent of audiologic performance (Zwolan et al., 2020).

Other evidence related to the NCA question was collected in several published retrospective reviews of medical records and cochlear implant data bases under various conditions. To gather the data pertinent to our analysis, we have contacted the authors of these studies to obtain the most precise information available, in order to determine if cochlear implantation may be reasonable and necessary for the treatment of adult Medicare beneficiaries with bilateral sensorineural hearing loss and who demonstrate pre-cochlear implant sentence recognition scores greater than 40% and less than or equal to 60% correct in the best-aided listening condition. Our requests to authors have been to obtain the individualized data regarding diagnoses and outcomes (as opposed to collective mean/median data) that describe the specific patient population of interest.

In the study by Lin et al. (2012), which reviewed 12 years of experience with cochlear implantation in older adults, HINT sentences (in quiet) were administered both pre-operatively and, except for one patient, approximately 1 year after the cochlear implant was activated (range 9–14 months). Patients were tested under binaural best-aided conditions pre-operatively, but post-operative speech scores were generally obtained under cochlear implant only conditions (with the exception of 9 individuals who were tested at 1 year under binaural best aided conditions).

Individualized results from this study were not reported in the article text; however, they were noted in graphic form. All the patients (n=17) whose pre-cochlear implant scores were between 40% and 60% correct did improve their HINT scores over time. Though improvement was variable, from the line diagram provided, almost all individuals achieved a one-year post-CI HINT score of 80% or better. Moreover, no one in this grouping exhibited a decline in their HINT scores one-year post surgery.

In the population studied by Dornhoffer et al. (2021), seven individuals exhibited pre-operative AzBio scores between 41% and 60%. Post-operatively one of these individuals exhibited significant improvement in their sentence recognition scores (post-operative score greater than the upper limit of 95% CI of pre-operative aided score) and six exhibited no significant change (post-operative score within 95% CI of pre-operative aided score). Of these six individuals, one patient's sentence recognition scores decreased 13% post-operatively, and five improved their sentence recognition scores in quiet between 2% and 15%. None of the patients with pre-operative sentence recognition scores between 41 and 60% demonstrated significant decline in their sentence recognition scores (post-operative score less than the lower limit of 95% CI of pre-operative aided score).

Since the publication of their article, we are also aware that the authors have collected the data of nine more patients with pre-operative sentence recognition scores between 41% - 60%; this data was obtained as described in the study. The pre-operative AzBio scores (in quiet) of these nine individuals ranged from 42% to 59%; post-operative scores in seven of the patients ranged from 70% to 99%. The scores of two patients decreased pre- to post-operatively from 53% to 49% and 58% to 43%, respectively.

The article by Dunn et al. (2020) demonstrated that many of those individuals with pre-operative AzBio scores in quiet and +10 dB SNR between 41% and 60%, do have significant improvement in their sentence scores post-operatively. Furthermore, the data gathered by these authors also suggested that speech perception benefit post-cochlear implantation is greatest in the qualifying condition (e.g. quiet, +10 dB SNR or +5 dB SNR). It is important to alert potential pre-operative implant candidates to this phenomenon.

Lundberg et al., 2021, retrospectively reviewed the medical records of 58 individuals with bilateral sensorineural hearing loss, who received their first cochlear implant at a tertiary care center cochlear implant program between June 2015 and December 2017. Sentence recognition testing was performed in quiet using AzBio sentence lists for each ear aided individually and bilaterally aided, and in noise using AzBio sentence lists tested at both +10 and + 5

dB SNR for each ear aided individually and aided bilaterally. Of the eight individuals who qualified for a cochlear implant in Group 2 (+10 Qualifiers) who exhibited a pre-op AzBio score in the cochlear implant ear in quiet between 41% and 60% and who were post-operatively re-tested in quiet between 10 and 14 months later, seven experienced an improvement in the implanted ear alone in quiet and one experienced a decrement (pre-operative score was 50% and post-operative score was 47%); but that one individual was also found to have an improved best aided score in quiet. Of the four +10 Qualifiers with pre-op AzBio scores in quiet between 41% and 60% whose post-operative best aided in quiet score was recorded, three improved post-operatively and one experienced a decrement (58% pre-op to 51% post-op). Of the five +10 Qualifiers with a pre-op AzBio score between 41% and 60% tested in the best aided condition at +10dB SNR, all improved in that noise level post–operatively.

Of the three patients in this study who qualified for cochlear implants with AzBio scores between 41% and 60% in +5 dB SNR noise, two improved sentence recognition scores in noise (one individual was not tested). In quiet though, one individual increased the sentence score pre- to post-operatively from 97% to 100%, one individual demonstrated a decrement in score from 94% to 82%, and one individual was not tested post-operatively for comparison.

In Mudery et al., 2017, the authors retrospectively reviewed candidacy and outcomes data for 136 cochlear implantation surgeries performed between January 2013 and September 2015 in patients with bilateral sensorineural hearing loss. Sentence recognition tests were performed using AzBio sentence scoring in the aided condition. Results were measured for monaural conditions (right hearing aid only, left hearing aid only) and the bilateral condition. If the patient performed greater than 40% in quiet in the best aided condition, further testing was conducted in the presence of noise (+ 10dB SNR or + 5dB SNR) in a step-wise fashion. Post-operative values were measured at least six months after surgery.

Ten patients demonstrated AzBio pre-operative scores in quiet between 41% and 60%, either in the aided implanted ear and/or aided bilateral condition. Most AzBio scores for the best aided condition of the implanted ear alone and the bilateral hearing condition in quiet and noise improved in the post-operative time period. But though one subject improved hearing in the implanted ear in quiet and noise, in the bilateral condition hearing declined in both conditions. This led the authors to speculate that the cochlear implant may be interfering with the binaural processing of sound. However, in another study participant, there was noted to be no change in performance pre-to-post-operatively for hearing in quiet in the implanted ear or in the bilateral condition, nor in noise bilaterally. However, this patient demonstrated worsened hearing in noise for the implanted ear.

In the retrospective chart review conducted by Perkins, et al., 2021, AzBio sentence scores in quiet and noise (+5 dB SNR) in the implanted ear and the bilateral-aided condition of individuals tested pre- and post-operatively were discussed. In general, statistically significant improvement was demonstrated for AzBio sentences in quiet and noise for the cochlear implant alone and bilateral listening conditions under the conditions of this study. Significant decrements in hearing, were infrequent in the range of our analysis.

In the retrospective study by Thai et al., (2022), the authors concluded (based on all the patients included in this study), that though cochlear implant patients qualifying in noise do show significant improvement in quiet and noise, they are less likely to benefit in speech recognition scores compared with those qualifying in quiet.

In Zhang and Coehlo (2018), the medical records of fifty-four individuals, aged 60 years of age or greater, were examined. These individuals exhibited bilateral moderate to profound sensorineural hearing loss and underwent unilateral cochlear implantation between January 2011 and November 2016. Sentence recognition was assessed using the AzBio test in the bilateral best aided condition. There were three subjects whose AzBio scores met the sentence scoring range of this NCA. All three subjects scores improved from pre- op to post-op in both quiet and noise (+5dB SNR).

The evidence discussed above describes the outcomes of individuals who would receive a cochlear implant if Medicare would expand its qualifying criteria as noted in this NCA. Inherent limitations to many of these studies is that sample sizes were small and all included subjects may not have represented the Medicare eligible population, though we believe the majority did. Also, only one study was prospectively conducted; that being Zwolan et al. (2020). In most of the cited studies, the information collection vehicles were clinical databases, not those established

specifically for research and therefore missing information was frequently noted. Sampling bias may also have been established due to the step-wise nature of testing protocols. Additionally, not all outcomes were reported in the same manner; some were reported in the best aided, binaural condition, while others were reported in the cochlear-implant only condition. Duration of hearing loss varied, and sometimes developed in early life. Moreover, some study subjects received unilateral implantation while others received bilateral cochlear implants. Adverse events were not systematically reported.

We also acknowledge the varying conditions under which sentence recognition testing was applied. For example, we are aware that some of these results were obtained with the HINT sentence recognition test and that, based on the results of Zwolan et al. (2020), if the AzBio testing had been provided, these subjects may have already qualified for cochlear implants under the 2005 policy. Still, cochlear implantation was associated with significantly improved sentence recognition in the Zwolan et al., (2020) study for all patients in Group I, including those whose AzBio scores at entrance were above 40%. Moreover, CMS requires no specific sentence recognition test to qualify for cochlear implantation so results demonstrating improved HINT scores can be meaningful.

The overarching question of this NCA is whether or not to expand our cochlear implantation criteria, so that beneficiaries who demonstrate sentence recognition test scores of > 40 % and ≤ 60 %, and their providers, no longer need to participate in appropriate trials in order to gain Medicare coverage for cochlear implantation.

The experience of hearing loss is singular, with the potential for a range of performance to be experienced in quiet and/or noise. Therefore, despite the limitations mentioned above, we believe that the available data as described indicates that many eligible individuals with pre-cochlear implant sentence recognition scores between 41% and 60% can improve their communication abilities with cochlear implantation and that this treatment would be reasonable and necessary under section 1862(a)(1)(A).

We are aware both through the results noted above, as well as by acknowledgement in the literature, that there exists variability of outcomes in noise and in quiet for individual patients who receive cochlear implants (Boisvert, Reis, Au, Cowan & Dowell, 2020; Zhao et al., 2020). Nonetheless, we do not know of any literature that allows a clinical prediction to be made in regards to the success or failure of cochlear implantation based on individualized characteristics (Boisvert et al., 2020; Velde, Rademaker, Damen, Smit & Stegeman,2021). This serves to emphasize the need for patient guidance with respect to the expectations for post implantation speech recognition outcomes. But we also are aware, as suggested by Dornhoffer et al. (2021), that since sensorineural hearing lost can be a progressive condition, the extent to which cochlear implants may preserve pre-operative aided speech recognition ability might be considered a successful outcome in those individuals that do not gain, but do not lose, clinically significant hearing. Furthermore, as discussed above, it has been noted by investigators that self-reported quality of life after cochlear implant can be independent of audiologic performance. Therefore, we are expanding the Medicare coverage criteria for cochlear implants to beneficiaries with bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence recognition.

We also are eliminating the requirement that the speech tests be administered by tape recordings, as this represents old technology. However, sentence recognition testing must still be presented in recorded formats to avoid the variability of human voice.

CMS also notes that additional Medicare coverage for cochlear implants for beneficiaries not meeting the coverage criteria may be available when performed in the context of FDA-approved category B investigational device exemption clinical trials as defined at 42 CFR 405.201 and when or as a routine cost in clinical trials under section 310.1 of the National Coverage Determinations Manual titled Routine Costs in Clinical Trials.

Health Disparities

The literature has reported that cochlear implantation is underused in the United States compared with other industrialized countries. Studies state that less than 10% of the population who are candidates for cochlear

implantation, receive the surgery. Obstacles that are noted to potentially stand in the way of individuals receiving consideration for this service include long distances from cochlear implant centers, large patient financial responsibilities for the implantation itself as well as related services, hospital monetary losses for the procedure, the lack of screening for hearing loss and low numbers of referrals for evaluation of cochlear implants by physicians who care for potential recipients of the device (Dornhoffer, Holcomb, Meyer, Dubno, & McRackan, 2020; Marinelli & Carlson, 2021).

The literature also reports that race may be significantly associated with time before cochlear implantation. For example, one university-based study demonstrated that those individuals identified with a non-white race (including African-American, Hispanic, Asian, and Native American patients) exhibited increased time to implantation compared with those individuals who identified as being of the white race. Authors note that white patients may be approximately six times more likely to undergo implantation during each year of hearing loss as compared to non-white patients. Such delays in undergoing surgery not only prolong patient disability but also may predict poorer treatment outcomes and therefore may represent a modifiable risk factor for cochlear implant candidates (Dornhoffer et al., 2020; Marinelli & Carlson, 2021).

Further research is required to describe the circumstances and patient characteristics that impede the delivery of cochlear implantation to those who can benefit from it. CMS believes the expansion of coverage criteria for cochlear implantation in our beneficiaries will serve to allow greater numbers of individuals to access this procedure earlier in their lives in order to more fully maintain their functional communication skills.

Summary

Based on the above discussion, CMS is amending NCD 50.3 by broadening the patient criteria for cochlear implantation and removing the restrictions that require participation in a research study for individuals with hearing test scores of > 40 % and ≤ 60 %. We believe the results of the evidence described above support this expansion.

IX. Conclusion

The Centers for Medicare & Medicaid Services (CMS) is reconsidering the national coverage determination established at section 50.3 of the Medicare National Coverage Determinations manual. We are expanding coverage by broadening the patient criteria and removing the requirement that for individuals with hearing test scores of > 40 % and ≤ 60 %, cochlear implantation may be covered only when the provider is participating in and patients are enrolled in either an FDA-approved category B IDE clinical trial, a trial under the CMS Clinical Trial Policy, or a prospective, controlled comparative trial approved by CMS. We have concluded that the evidence is sufficient to determine that cochlear implantation may be covered for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence cognition. Patients must meet all of the following criteria.

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
- No contraindications to surgery; and
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

CMS may also provide coverage of cochlear implants for beneficiaries not meeting the coverage criteria listed above when performed in the context of FDA-approved category B investigational device exemption clinical trials as defined at 42 CFR 405.201 or as a routine cost in clinical trials under section 310.1 of the National Coverage Determinations Manual titled Routine Costs in Clinical Trials.

See Appendix B for the draft manual language.

APPENDIX A

General Methodological Principles of Study Design

(Section VI of the Decision Memorandum)

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to that group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is to the extent that differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are

important factors as well. For example, a well-designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of that have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

Randomized controlled trials
Non-randomized controlled trials
Prospective cohort studies
Retrospective case control studies
Cross-sectional studies
Surveillance studies (e. g. , using registries or surveys)
Consecutive case series
Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in that confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and consider the evidence.

Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to that the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare

coverage determinations. One of the goals of our determination process is to assess health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived. Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

APPENDIX B
Medicare National Coverage Determinations Manual

Draft

This draft NCD is subject to formal revisions and formatting changes prior to the release of the final NCD contractor instructions and publication in the Medicare National Coverage Determinations Manual.

Table of Contents
(Rev.)

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

B. Nationally Covered Indications

Effective for services performed on or after September 26, 2022, cochlear implantation may be covered for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence cognition. Patients must meet all of the following criteria.

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;

- No contraindications to surgery; and
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

C. Nationally Non-Covered Indications

Medicare beneficiaries not meeting all of the coverage criteria for cochlear implantation listed in Section B are deemed not eligible for Medicare coverage except as described in Section D below.

D. Other

CMS may provide coverage of cochlear implants for beneficiaries not meeting the coverage criteria listed in Section B when performed in the context of FDA-approved category B investigational device exemption clinical trials as defined at 42 CFR 405.201 or as a routine cost in clinical trials under section 310.1 of the National Coverage Determinations Manual titled Routine Costs in Clinical Trials.

APPENDIX C—NCD 50.3 (2005)

50.3 - Cochlear Implantation (Effective April 4, 2005)
(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10,
Implementation: Upon Implementation of ICD-10)

A. General

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

B. Nationally Covered Indications

1. Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for treatment of bilateral pre- or-post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition. Medicare coverage is provided only for those patients who meet all of the following selection guidelines.
    - Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
    - Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
    - Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
    - No contraindications to surgery; and
    - The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.
2. Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for individuals meeting the selection guidelines above and with hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption clinical trial as defined at 42 CFR 405.201, a trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.

C. Nationally Non-Covered Indications

Medicare beneficiaries not meeting all of the coverage criteria for cochlear implantation listed are deemed not eligible for Medicare coverage under section 1862(a)(1)(A) of the Social Security Act.

D. Other

All other indications for cochlear implantation not otherwise indicated as nationally covered or non-covered above remain at local A/B MAC discretion.

Bibliography

American Academy of Audiology Task Force on Cochlear Implant Practices. Clinical Practice Guideline: Cochlear Implants. July, 2019. Accessed on 1/14/2022 at: https://www.audiology.org/wp-content/uploads/2021/05/CochlearImplantPracticeGuidelines.pdf

Benoiton LA, MacLachlan AL, Mustard J, Jayawardana J, Bird P. Classification of cochlear implant complications using a modified Clavien-Dindo classification [published online ahead of print, 2022 Jul 11]. Cochlear Implants Int. 2022;1-9. doi:10.1080/14670100.2022.2096193

Boisvert I, Reis M, Au A, Cowan R, Dowell RC. Cochlear implantation outcomes in adults: A scoping review. PLoS One. 2020;15(5):e0232421. Published 2020 May 5. doi:10.1371/journal.pone.0232421.

Buchman CA, Gifford RH, Haynes DS, et al. Unilateral Cochlear Implants for Severe, Profound, or Moderate Sloping to Profound Bilateral Sensorineural Hearing Loss: A Systematic Review and Consensus Statements. JAMA Otolaryngol Head Neck Surg. 2020 Oct 1;146(10):942-953. doi: 10.1001/jamaoto.2020.0998. PMID: 32857157.

CAG - 00107N, Cochlear Implantation, 2005. Accessed on June 3, 2022 at https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=134.

Carlson ML. Cochlear Implantation in Adults. N Engl J Med. 2020 Apr 16;382(16):1531-1542. doi: 10.1056/NEJMra1904407. PMID: 322943.

Cunningham LL, Tucci DL. Hearing Loss in Adults. N Engl J Med. 2017 Dec 21;377(25):2465-2473. doi: 10.1056/NEJMra1616601. PMID: 2926227.

Dornhoffer JR, Holcomb MA, Meyer TA, Dubno JR, McRackan TR. Factors Influencing Time to Cochlear Implantation. Otol Neurotol. 2020 Feb;41(2):173-177. doi: 10.1097/MAO.0000000000002449. PMID: 31923156; PMCID: PMC7577180.

Dornhoffer JR, Reddy P, Meyer TA, Schvartz-Leyzac KC, Dubno JR, McRackan TR. Individual Differences in Speech Recognition Changes After Cochlear Implantation. JAMA Otolaryngol Head Neck Surg. 2021 Mar 1;147(3):280-286. doi: 10.1001/jamaoto.2020.5094. PMID: 33410869.

Dunn C, Miller SE, Schafer EC, Silva C, Gifford RH, Grisel JJ. Benefits of a Hearing Registry: Cochlear Implant Candidacy in Quiet Versus Noise in 1,611 Patients. Am J Audiol. 2020;29(4):851-861. doi:10.1044/2020_AJA-20-00055.

Feigenbaum E. Health Technology Assessment Series: Public Health Service Assessment - Cochlear Implant Devices

for the Profoundly Hearing Impaired, 1986. Accessed on 6/3/2022 at https://ia803000.us.archive.org/3/items/cochlearimplantd00feig/cochlearimplantd00feig.pdf.

Health Quality Ontario. Bilateral Cochlear Implantation: A Health Technology Assessment. Ont Health Technol Assess Ser. 2018;18(6):1-139. Published 2018 Oct 24.

Hearing Aids and Auditory Implants. Medicare Benefit Policy Manual. Chapter 16, Section 100 (Rev. 39; Issued: 11-10-05; Effective: 11-10-05; Implementation: 12-12-05). Accessed on 6/10/22 at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf

Layfield E, Hwa TP, Naples J, et al. Failure and Revision Surgery After Cochlear Implantation in the Adult Population: A 10-year Single-institution Retrospective and Systematic Review of the Literature. Otol Neurotol. 2021;42(3):408-413. doi:10.1097/MAO.0000000000002940

Lin FR, Chien WW, Li L, Clarrett DM, Niparko JK, Francis HW. Cochlear implantation in older adults. Medicine (Baltimore). 2012; 91(5):229-241. doi:10.1097/MD.0b013e31826b145a. PMID: 22932787.

Lundberg EMH, Strong D, Anderson M, Kaizer AM, Gubbels S. Do Patients Benefit From a Cochlear Implant When They Qualify Only in the Presence of Background Noise?. Otol Neurotol. 2021;42(2):251-259. Doi:10.1097/MAO.0000000000002878.

Mahboubi H, Lin HW, Bhattacharyya N. Prevalence, Characteristics, and Treatment Patterns of Hearing Difficulty in the United States. JAMA Otolaryngol Head Neck Surg. 2018 Jan 1;144(1):65-70. doi: 10.1001/jamaoto.2017.2223. PMID: 29167904.

Marinelli JP, Carlson ML. Barriers to Access and Health Care Disparities Associated With Cochlear Implantation Among Adults in the United States. Mayo Clin Proc. 2021 Mar;96(3):547-549. doi: 10.1016/j.mayocp.2020.08.027. PMID: 33673908.

Michels TC, Duffy MT, Rogers DJ. Hearing Loss in Adults: Differential Diagnosis and Treatment. Am Fam Physician. 2019 Jul 15;100(2):98-108. PMID: 31305044.

Mudery JA, Francis R, McCrary H, Jacob A. Older Individuals Meeting Medicare Cochlear Implant Candidacy Criteria in Noise but Not in Quiet: Are These Patients Improved by Surgery? Otol Neurotol. 2017;38(2):187-191. doi:10.1097/MAO.0000000000001271.

Naples JG, Ruckenstein MJ. Cochlear Implant. Otolaryngol Clin North Am. 2020 Feb;53(1):87-102. doi: 10.1016/j.otc.2019.09.004. Epub 2019 Oct 31. PMID: 31677740.

NIDCD: Cochlear Implant. National Institute on Deafness and Other Communication Disorders. NIH Publication No. 00-4798; February 2016 with statistical update March 2021. Accessed on 5/10/2022 at https://www.nidcd.nih.gov/health/cochlear-implants

NIDCD Fact Sheet Hearing and Balance: Age-Related Hearing Loss. National Institute on Deafness and Other Communication Disorders. NIH Pub. No. 97-4235; March 2016. Accessed on 1/11/2022 at https://www.nidcd.nih.gov/sites/default/files/Documents/health/hearing/AgeRelatedHearingLoss.pdf

NIDCD Fact Sheet Hearing and Balance: Cochlear Implants. National Institute on Deafness and Other Communication Disorders. NIH Publication No. 00-4798; February 2016. Accessed on 1/11/2022 at https://www.nidcd.nih.gov/sites/default/files/Documents/health/hearing/CochlearImplants.pdf

Perkins E, Dietrich MS, Manzoor N, et al. Further Evidence for the Expansion of Adult Cochlear Implant Candidacy Criteria. Otol Neurotol. 2021;42(6):815-823. doi:10.1097/MAO.0000000000003068.

Prentiss S, Snapp H, Zwolan T. Audiology Practices in the Preoperative Evaluation and Management of Adult Cochlear Implant Candidates. JAMA Otolaryngol Head Neck Surg. 2020;146(2):136-142. doi:10.1001/jamaoto.2019.3760.

Thai A, Tran E, Swanson A, et al. Outcomes in Patients Meeting Cochlear Implant Criteria in Noise but Not in Quiet. Otol Neurotol. 2022;43(1):56-63. doi:10.1097/MAO.0000000000003351.

Varadarajan VV, Sydlowski SA, Li MM, Anne S, Adunka OF. Evolving Criteria for Adult and Pediatric Cochlear Implantation. Ear Nose Throat J. 2021 Jan;100(1):31-37. doi: 10.1177/0145561320947258. Epub 2020 Aug 17. PMID: 32804575.

Velde HM, Rademaker MM, Damen J, Smit AL, Stegeman I. Prediction models for clinical outcome after cochlear implantation: a systematic review. J Clin Epidemiol. 2021;137:182-194. doi:10.1016/j.jclinepi.2021.04.005.

Zhang E, Coelho DH. Beyond Sentence Recognition in Quiet for Older Adults: Implications for Cochlear Implant Candidacy. Otol Neurotol. 2018;39(8):979-986. doi:10.1097/MAO.0000000000001885.

Zhao EE, Dornhoffer JR, Loftus C, et al. Association of Patient-Related Factors With Adult Cochlear Implant Speech Recognition Outcomes: A Meta-analysis. JAMA Otolaryngol Head Neck Surg. 2020;146(7):613-620. doi:10.1001/jamaoto.2020.0662.

Zwolan TA, Basura G. Determining Cochlear Implant Candidacy in Adults: Limitations, Expansions, and Opportunities for Improvement. Semin Hear. 2021;42(4):331-341. Published 2021 Dec 9. doi:10.1055/s-0041-1739283. PMID: 34912161.

Zwolan TA, Kallogjeri D, Firszt JB, Buchman CA. Assessment of Cochlear Implants for Adult Medicare Beneficiaries Aged 65 Years or Older Who Meet Expanded Indications of Open-Set Sentence Recognition: A Multicenter Nonrandomized Clinical Trial. JAMA Otolaryngol Head Neck Surg. 2020 Oct 1;146(10):933-941. doi: 10.1001/jamaoto.2020.2286. PMID: 32857106.