

October 27, 2020

Centers for Medicare & Medicaid Services
Director, Coverage & Analysis Group
7500 Security Blvd.
Baltimore, MD 21244

Re: Formal request for NCD Reconsideration

Dear Director:

We ask that you consider this formal request for NCD Reconsideration regarding the National Coverage Determination for Cochlear Implantation (5-0.3), which has been in existence since April 4, 2005. The current NCD states the following:

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 cues 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.

Based on the evidence provided in this request, we are seeking 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”. We are not requesting any other changes to the NCD. This request in writing fulfills all of the requirements of a formal request for NCD Reconsideration as outlined in the Federal Register, Volume 78, No. 152 published on August 7, 2013.

DESCRIPTION OF THE ITEM: Cochlear Implants

A cochlear implant is an electronic device that provides improved hearing and communication to children and adults with significant hearing loss. Cochlear implants currently consist of both surgically implanted internal components that are coupled to externally worn components. The surgically implanted portion of the cochlear implant includes: an electrode array, receiver/stimulator, a transmitter/receiver coil, and magnet. The externally worn portion includes the following: a microphone (picks up sound from the environment), a speech processor that converts the sounds picked up by the microphone to an electric signal, and a transmitter/receiver coil that sends the signal from the speech processor to the implanted device. The implanted receiver/stimulator receives the signal from the sound processor and converts it to electric impulses that are delivered to the surgically implanted electrodes. The electrodes stimulate the inner ear in a pattern determined by the speech coding strategy employed by the sound processor. An example of a contemporary cochlear implant system is provided in Figure 1.

Figure 1. Photo provided courtesy of Cochlear Americas

RELEVANCE, USEFULNESS AND BENEFITS OF COCHLEAR IMPLANTS FOR MEDICARE BENEFICIARIES

Cochlear implants were first approved by the FDA for widespread use in adults in 1984. Medicare has covered cochlear implants since 1986. Since that time, numerous advances have taken place in regards to the technological, clinical, and surgical aspects of these devices, all of which have resulted in improved outcomes for cochlear implant recipients.

The benefits of cochlear implant are clear, and they have become the standard of care for treating both children and adults with significant bilateral hearing loss. Cochlear implants are highly effective and useful for improving communication. According to the FDA (FDA website accessed October 7, 2020), most adults demonstrate benefit immediately and performance may continue to improve for several years; children also demonstrate benefit although they may improve at a slower pace; most recipients perceive loud, medium, and soft sounds; many understand speech without lipreading; many can make telephone calls; many can watch TV more easily; and some enjoy music. Numerous articles have documented the benefits of improved speech recognition in quiet, improved speech recognition in noise, reduction in tinnitus, and improvements in quality of life. A recent systematic review and consensus statement summarized many of these benefits in adults (Buchman et al., 2020).

As described below in the section titled “Clinical Evidence Supporting Clinical Indications for Cochlear Implants”, many publications provide evidence of the effectiveness of cochlear implants in the Medicare population, and many specifically address the outcomes received by Medicare-eligible beneficiaries who obtain preoperative sentence recognition scores that exceed 40%. Articles pertaining to each of these areas are provided in the Reference list and copies of instrumental articles are provided in the Appendix of this request.

DESIGN, PURPOSE, AND METHOD OF USING COCHLEAR IMPLANTS AS RELATED TO THIS REQUEST

As indicated previously, Medicare's current NCD covers cochlear implants for beneficiaries who demonstrate a score "less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence recognition". We believe the proven efficacy of this technology warrants reconsideration of this NCD to include Medicare beneficiaries with slightly better pre-operative speech recognition scores. This is based on published studies with strong evidence demonstrating that patients who score between 40 and 60% correct preoperatively on a sentence measure in their best-aided condition tend to demonstrate improved speech recognition with a cochlear implant

It is important to note that the Nucleus 24 device, as well as numerous subsequent devices manufactured by Cochlear Americas, have had FDA approval for use of their devices in patients whose scores equal those in the requested expansion of the NCD since the year 2000. Their indications include approval for patients who score less than or equal to 60% correct on sentences in the best aided condition.

It is important to note that expansion of Medicare's current NCD to include patients with greater preoperative speech recognition scores may result in greater outcomes for cochlear implant recipients. Dowell et al (2016) found that chances of a good outcome are significantly better if implantation occurs relatively soon after onset of severe hearing loss and before the loss of all functional auditory skills. Patients who meet the current NCD by obtaining a best-aided sentence score less than 40% means they are missing more than 60% of conversations. Expanding this score to 60% will make it more likely that patients will receive an implant prior to the loss of all functional auditory skills.

Several important steps have been taken to prepare for this request for reconsideration of the NCD. In July 2013, the American Cochlear Implant Alliance submitted a proposal to CMS to investigate expansion of the current NCD. The Coverage with Evidence (CED) study was approved and covered the use of cochlear implants in Medicare-eligible beneficiaries with preoperative hearing test sentence score in quiet that fell between 41 and 60% correct in the best aided listening condition. This study was registered with clinicaltrials.gov as NCT02075229. In September, 2015, the protocol change was approved by CMS to replace the sentence test measure of HINT sentences with the more widely-used AzBio Sentences for candidacy determination and outcome measurement. In September, 2018, an interim review of the data was presented to CMS. In August, 2019, a final analysis of the data was presented to CMS. Finally, the results of the CED study were published in *JAMA Otolaryngology* in August, 2020 (Zwolan et al 2020). We have provided copies of the slides presented to CMS in 2019 as well as a copy of the *JAMA-OTO* publication in the Appendix of this formal request.

STATUTORILY DEFINED BENEFIT CATEGORY

Cochlear implants currently fall within the benefit category of prosthetic devices under section 1861(s)(8) of the Social Security Act. The requested update to the NCD would not impact the defined benefit category. In regards to coverage, cochlear implant surgeries are typically performed as an outpatient procedure and primarily fall under Medicare Part B. Medicare Part C plans also cover cochlear implants when medically necessary.

MEDICAL INDICATIONS FOR USE

The current FDA-approved indications for adults for the three device manufacturers who provide cochlear implants in the United States (Advanced Bionics (Sylmar, CA), Cochlear Ltd. (Sydney, Australia), and MedEL (Innsbruck, Austria)) may be found at www.fda.org.

CLINICAL EVIDENCE SUPPORTING CLINICAL INDICATIONS FOR COCHLEAR IMPLANTS

Numerous investigators have reported outcomes obtained with adults who use cochlear implants. One of the most comprehensive reviews of this topic was recently published in JAMA Otolaryngology (Buchman et al., 2020). This study consisted of a modified Delphi consensus process that a systematic review of the literature and discussions among experts to develop statements about cochlear implants for severe, profound, or moderate sloping to profound bilateral sensorineural hearing loss. As a result, 20 consensus statements dealing with 7 key areas of interest were developed: 1) level of awareness of cochlear implantation, 2) best practice clinical pathway from diagnosis to surgery, 3) best practice guidelines for surgery 4) clinical effectiveness of cochlear implantation, 5) factors associated with postimplantation outcomes, 6) association between hearing loss and depression, cognition, and dementia, and 7) cost implications of cochlear implantation.

The above-mentioned publication includes 4 statements related to the effectiveness of cochlear implants. **Statement 7:** Cochlear implants significantly improve speech recognition in both quiet and moderate noise in adults with severe, profound, or moderate sloping to profound bilateral sensorineural hearing loss (SNHL); these gains in speech recognition are likely to remain stable over time. **Statement 8:** Both word and sentence recognition tests should be used to evaluate speech recognition performance after cochlear implantation. **Statement 9:** Cochlear implants significantly improve overall and hearing-specific quality of life (QOL) in adults with severe, profound, or moderate sloping to profound bilateral SNHL. **Statement 10:** Adults who are eligible for cochlear implants should receive the implant as soon as possible to maximize postimplantation speech recognition. Additionally, the publication includes 3 statements related to the association between hearing loss and depression, cognition, and dementia. **Statement 15:** Adults with hearing loss can be substantially affected by social isolation, loneliness, and depression; evidence suggests that treatment with cochlear implants can lead to improvement in these aspects of well-being and mental health. Longitudinal studies are needed to obtain further knowledge in this area. **Statement 16:** There is an association between age-related hearing loss and cognitive or memory impairment. **Statement 17:** Further research is required to confirm the nature of cognitive impairment in individuals with hearing loss and its potential reversibility with treatment. **Statement 18:** The use of cochlear implants may improve cognition in older adults with bilateral severe to profound SNHL. **Statement 19:** Hearing loss is not a symptom of dementia; however, treatment of hearing loss may reduce the risk of dementia. We have included a copy of this comprehensive study in the Appendix.

Another recent review of adult outcomes was recently published by Boisvert et al (2020). This paper included a review of 201 articles deemed appropriate for inclusion in the review by the authors. The authors concluded that “Despite broad inconsistencies in measurement, research design, and reporting across articles, it is evident that cochlear implantation is beneficial to the majority of adults of any age who have limited speech perception abilities”. We have included a copy of this review in the Appendix.

Important advances in technology have taken place since the current NCD was approved in 2005. These advances have led to improvements in outcomes obtained by adults after receiving a cochlear implant. One of the largest, most comprehensive and up-to-date clinical trials of adult outcomes was recently published by Buchman et al. (2020), in JAMA-Otolaryngology. This clinical trial of the Nucleus CI532 device included data for 96 adults with a median age at cochlear implantation of 71 years. Pre-operatively, participants demonstrated median CNC word and AzBio sentence in noise scores of 14.6 and 14.8%, respectively. Median scores on these measures improved to 60.9 % on CNCs (46.3 % improvement) and 42.7 % on AzBio Sentences in noise (27.9% improvement). Scores were even higher when participants were able to utilize a hearing aid on the contralateral ear. When tested in their best-aided condition, participants scores increased to 69.8% on CNC words and 57.7% on AzBio Sentences in noise. We have included a copy of this manuscript in the Appendix.

Perhaps more applicable to the CMS NCD for cochlear implants is the recent publication of Wick et al. (2020), where 70 participants over the age of 65 years from the Nucleus CI532 trial mentioned above were specifically evaluated to examine hearing and quality of life outcomes following cochlear implantation. Similar to the overall CI532 findings, they reported a mean improvement in CNC scores of 37.2% and 44.1% in the implant alone and bimodal conditions, respectively. Sentence recognition scores in noise improved by 24.5% in the implant alone condition and by 21.6% in the bimodal condition. Additionally, significant improvements were noted in Health Utility Index (HUI) scores and Speech, Spatial, and Qualities (SSQ) of Hearing Scale scores for this population. We have included a copy of this manuscript in the Appendix. Similar to CMS indications, participants in the CI532 study were required to demonstrate a bilateral moderate to profound sensorineural hearing loss. It should be noted that candidacy was based on a word score in quiet rather than a sentence score in quiet. In the CI532 study, participants demonstrated preoperative word scores of 40% correct or less in the ear undergoing implantation and 50% or less in the contralateral ear.

Zwolan et al (2014) also reported on results of a multicenter clinical trial, with special analysis of health utility and performance, based on participants' age at implant. They found that older subjects demonstrated a greater mean improvement on the HUI Hearing subset than younger participants when preimplant and 12 month post-implant scores were compared, despite demonstrating slightly less improvement in mean speech recognition scores during this timeframe. Importantly, some Medicare beneficiaries were enrolled in this study who fall into the speech recognition category analyzed in the CED related to this request: nine subjects in the Zwolan et al. study met part 2 of the current NCD (enrollment in a category B investigational device exemption clinical trial) and obtained scores greater than 40% on open-set sentences prior to receiving their cochlear implant. This group demonstrated significant postimplant improvement on all measures except the HINT sentences in quiet. This was not surprising, given the higher preimplant scores obtained by these subjects and the reported ceiling effects noted for this test by Gifford et al. (2008). The studies mentioned above provide further evidence to support this requested change in the current NCD.

CMS-APPROVED CLINICAL TRIAL: EVIDENCE TO SUPPORT RECONSIDERATION OF THE NCD

The results of a CMS-approved clinical trial that evaluated safety and performance of cochlear implants when provided to CMS-eligible beneficiaries who met expanded indications demonstrated that expansion of the CMS NCD for cochlear implants is appropriate. The results of this trial are summarized

in the attached handout of slides that were presented to the CMS Coverage & Analysis Group in August, 2019, as well as in the attached copy of the peer reviewed manuscript that was recently published in JAMA-Otolaryngology in August, 2020 that summarizes this clinical trial (Zwolan et al, 2020). This study included 34 CMS-eligible beneficiaries enrolled into the study at various cochlear implant programs across the United States. The study examined pre- and post-operative word and sentence recognition, as well as telephone recognition, and self-reported device benefit, health utility and quality of life. As noted in the attached materials, participants in this study demonstrated significant improvements in both word and sentence recognition when 6 and 12 month post-implant scores obtained for both the implant alone and best aided conditions were compared to scores obtained pre-operatively using hearing aids in their best aided condition and in the ear to be implanted. Subjects demonstrated significant and meaningful improvements in sentence recognition: median improvement of 36% (range = -22 to 75% with a lower bound of 1-sided 95% confidence interval = 31%) for the best aided condition and median improvement of 53% (range = -15 to 95% with a lower bound of 1-sided 95% CI =45%) for the implant ear alone condition. The scores obtained on the telephone test improved from a pre-operative median of 28% to a median score of 97% (estimated marginal mean difference of 50.1% [95% CI, 35.7-64.6%]) 12 months post-implant. In addition, these improvements in speech recognition appear to be related to positive changes on self-reported assessments of health utility and device benefit. These benefits were noted both for patients who demonstrated a pre-operative sentence recognition score of 41-50% and for those who demonstrated a score that fell between 51 and 60% correct on AzBio sentences in their best-aided condition.

In the presentation given to Medicare Coverage & Analysis Group in August, 2019, similarities between the above-mentioned CED and the comprehensive Cochlear Corporation CI 532 Study (Buchman et al., 2020) were pointed out (see slides 42-48). First, correlation analysis was performed to determine the relationship between pre-operative AzBio and CNC Word scores in the best aided condition. This was needed since the two studies utilized different inclusion metrics (the CI 532 study utilized a word score while the CMS CED utilized a sentence score). The analysis determined that a vast majority of the participants enrolled in the CMS CED demonstrated CNC word scores that fell at or above 20% (slide 42). Examination of the CI 532 study cohort revealed that 70 of 100 participants in the CI 532 trial were 65 years of age or older. Of these 70 participants, 49 had preoperative CNC best-aided scores greater than 20%. Subsequently, data for the 49 participants in the CI532 study was compared to data obtained for the 31 participants in the CMS CED study. Baseline characteristics and baseline measures of these two groups of participants were compared (slides 44, 45). Additionally, scores obtained 6 months post-implant were compared for the two groups (as the CI 532 trial lasted 6 months) and revealed that each group demonstrated significant improvement in CNC word recognition in both their best-aided and implant ear alone conditions. Changes in word recognition did not differ significantly between the two study groups (slide 46). Both groups of participants demonstrated significant changes in scores on the HUI Hearing and HUI Multi over time (slide 47). Participants in the CI532 study demonstrated lower scores preoperatively than participants in the CMS CED, and changes demonstrated over time were significantly greater for the CI 532 participants. Additionally, both groups demonstrated a significant change in HUI speech and HUI dexterity scores, but differences between groups were not significant. This comparison with data collected as part of a nationwide clinical trial further supports the findings of improvement performance and improvement in QOL as noted in the CMS CED (Zwolan et al., 2020).

Furthermore, the results obtained by participants in the CMS-approved study are highly consistent with those of Wick et al (2020), which focused on participants 65 years and older, and were also enrolled in the Nucleus CI532 clinical trial. Comparison of these two studies indicate that participants demonstrated 6 month post-implant CNC word scores of 61% (CI532 trial) and 62% (CMS trial). In the best-aided condition, scores improved to 72% for the CI532 participants and 78% for the CMS participants. This indicates the results obtained in the CMS trial are representative of outcomes being obtained by cochlear implant recipients throughout the United States. The improvements obtained by participants in these studies resulted in significant improvements in quality of life in addition to improvements in communication. As Wick et al (2020) indicate, these outcomes may facilitate a concept of healthy aging.

PROPOSED USE OF THE ITEM

Cochlear implants are designed to provide improved communication to adults and children with significant hearing loss. Current devices are designed to be used all waking hours in order to provide the user with hearing and improved communication.

TARGET MEDICARE POPULATION

The target Medicare population to receive a cochlear implant includes adults with significant bilateral hearing loss. It is important to treat hearing loss in Medicare beneficiaries as it can significantly impact several factors. When compared to outcomes received with hearing aids by adults with significant hearing loss, cochlear implants have been demonstrated to provide improved sound clarity (Caldwell et al., 2017; Novak et al., 2000) , improvements in speech recognition (Zwolan et al., 2020; Buchman et al., 2020; Hirschfelder et al, 2008;), improved hearing in noise (Hirschfelder et al, 2008), enhanced employment opportunities (Wyatt et al., 1996;), improvements in quality of life (Zwolan et al., 2020; Mo et al., 2005; Manrique-Huarte et al., 2016; and improved overall health (Manrique-Huarte et al., 2016).

INTENDED USE FOR MEDICARE BENEFICIARIES

Cochlear implants are intended for use by Medicare beneficiaries. Health care providers are involved in the care of patients who receive cochlear implants in a variety of ways. Audiologists are trained to evaluate candidacy for a cochlear implant (evaluate the appropriateness of current hearing aids, perform speech recognition testing), perform post-operative programming of the device, provide instruction to the beneficiary regarding use and care of the device, evaluate post-operative performance, and collaborate with other professionals to ensure the needs of the patient are being met. Surgeons also play a role in determining candidacy for a cochlear implant, including determination of medical suitability for the procedure, examination of radiographic studies, and collaboration with the audiologist regarding pre-operative test results. The surgeon performs surgical placement of the device, provides any needed post-operative medical follow-up, and continues to coordinate with the audiologist to ensure adequate progress and continued device benefit. A speech language pathologist is often involved in patient care, and may be involved in pre-operative determination of candidacy and post-operative evaluation of performance. Additionally, the speech language pathologist is often involved in providing aural rehabilitation to help maximize outcomes with the device.

SUMMARY

We believe the attached documents and the descriptions above provide sufficient evidence to support this formal request to reconsider the NCD for cochlear implants to include patients with slightly better speech recognition when tested in their best aided condition. At this time, we are not requesting a change in the wording related to hearing loss.

PROPOSED RECONSIDERATION

Based on the provided evidence, and based on the results of the CMS-approved clinical trial, we would like to propose CMS consider the following wording to replace current wording of the NCD for cochlear implants:

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 tape-recorded tests of open-set sentence recognition. 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.

SUPPORTING DOCUMENTATION

Attached to this letter are the following documents:

1. A copy of the manuscript recently published in JAMA- Otolaryngology titled “Assessment of Cochlear Implants for Adult Medicare Beneficiaries Aged 65 Years or Older Who Meet Expanded Indications of Open-Set Sentence Recognition” that summarizes the CMS-approved clinical trial related to this formal NCD request.
2. A copy of the slide deck presented to the Coverage and Analysis Group of CMS on August 27, 2019 summarizing the findings of the CMS-approved CED study titled “An Evaluation of Revised Indications for Cochlear Implant Candidacy for the Adult CMS Population”.
3. A copy of a recent paper published in JAMA Otolaryngology that summarizes current outcomes in adults with current technology as reported for the Nucleus Ci532 clinical trial (Buchman et al, 2020).
4. A copy of a recent paper, also published in JAMA Otolaryngology, that focuses on outcomes obtained by 70 adults who were 65 years and older who were enrolled in the Nucleus CI532 trial (Wick et al., 2020).
5. A copy of the Delphi Consensus paper published in 2020 (Buchman et al).

6. A copy of the paper published by Boivert et al. (2020) that summarizes recent outcomes with adult cochlear implant recipients.
7. A list of references that provide supporting evidence to support this request for reconsideration of the current NCD.

Thank you for considering this formal request. Please do not hesitate to contact us if you have any questions or desire additional information.

Sincerely,

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