March 29, 2022

Dear CMS:

Dr. Craig Buchman and I would like to begin by thanking CMS for opening the national coverage determination analysis for the reconsideration of cochlear implantation. Reaching this point has taken several years and represents hard work and dedication of numerous professionals and adults with hearing loss who believe strongly that CMS coverage for cochlear implants needs to be expanded.

As you know, we submitted a formal request for NCD reconsideration on October 27, 2020 asking that the NCD be changed to expand coverage to beneficiaries who score “less than or equal to 60% correct in the best-aided listening condition on tape-recorded tests of open-set sentence recognition”. This is not a drastic request, and represents the wording previously approved by CMS in April 2005 for this population in Part 2 of the current NCD, which states “...cochlear implantation may be covered for individuals meeting hearing test scores of greater than 40% and less than or equal to 60% only when the provide in 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”.

In our application, we provided clinical evidence to support the NCD reconsideration request, including description of the findings of the Coverage with Evidence study (NCT02075229) that were published in JAMA Otolaryngology in August 2020 (Zwolan et al, 2020). Numerous other publications were also cited in the reconsideration request. Since the request was submitted, additional publications dealing with this important topic have appeared in the literature or have come to light that deserve mention here.

In our reconsideration request, we cited the study by Dowell et al (2016) who reported 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. Research to further support these findings was published by Miller et al (2020) in the Journal of the American Academy of Audiology. This group examined whether insurance payer status affected access to cochlear implant services and longitudinal speech perception outcomes in adult cochlear implant recipients. They cited the important differences that exist between coverage indications for public and private insurers - Medicare’s strict requirement of a best-aided sentence score less than 40% whereas most private insurers follow the FDA qualifying criteria that allow speech perception scores up to 60%. They found that publicly insured patients were predicted to have longitudinal CNC scores in quiet that are 15% poorer than those with private insurance and sentence in noise scores that are 11% poorer, even when differences in age at implantation was controlled for across the insurance cohorts. They indicate these differences were likely impacted by the finding that patients with public insurance tended to wait longer to receive their devices, which is typical in clinical care when patients are required to demonstrate lower speech perception scores. Importantly, their prediction model indicated that having public insurance could lead to disparities in hearing health care.

Such disparities for patients with Medicare are evident in clinical practice, where patients are denied access to cochlear implants solely based on their insurer. If presented with two patients with identical audiometric test results (i.e., a sentence recognition score of 52%), we are able to provide the CI to the patient with private insurance (because they typically follow the FDA requirement of a score less than 60%) but must deny the implant to the patient with Medicare. It seems unfair to tell CMS beneficiaries
that their hearing is “too good” for a cochlear implant when they’re missing up to 60% of what is being said. This not only leads to disparities in health care but also prolongs the time the CMS beneficiary is deprived of optimized hearing and based on published research, negatively impacts their outcome once they qualify for a CI. Changing the NCD to better align with FDA indications will decrease such disparities and will likely improve the outcomes being received by patients with CMS coverage who receive a cochlear implant. And, expanding the NCD to include adults with a pre-operative sentence score of up to 60% correct in the best-aided condition resulted in significant improvements in speech recognition (Zwolan et al., 2020). This has since been noted by others.

In 2020, Barnes et al published a study in Laryngoscope that reviewed the pre-operative pure-tone thresholds and speech perception scores in the ipsilateral and contralateral ear of adult CI recipients and looked at the impact that existing insurance paradigms have on CI candidacy. Specifically, these authors focused on the binaural best-aided requirements and stated, “This limitation likely leads to worse device performance as patients often wait years for their binaural hearing to qualify while their ear to be implanted potentially experiences an unnecessarily extended duration of deafness”. They also noted that “Older patients also experience a unique delay in referral for cochlear implantation”. Such delays are likely influenced by the widespread recognition that Medicare indications are stricter than those of private insurers, resulting in delayed referral. Calls for greater awareness of the benefits of cochlear implantation, the need for early referral, and improved accessibility to CI for Medicare beneficiaries have been cited by others (Holder et al, 2018; Mudery et al, 2017; Zhang et al, 2018).

Finally, one additional area of research that deserves mention is the value that improved hearing brings to brain function. Frank Lin and colleagues (2013) examined cognitive impairment scores of nearly 2,000 seniors over a six-year period and found that seniors with hearing loss were 24% more likely to meet a clinical description of cognitive impairment than the comparative group of seniors with normal hearing. More recently, a comprehensive study of more than 82,000 adults over the age of 59 revealed that insufficient and poor speech-in-noise hearing were associated with a 61% and 91% increased risk of developing dementia, when compared to normal speech-in-noise hearing, respectively (Stevenson et al., 2021), and that speech-in-noise hearing impairment could represent a promising target for dementia prevention. Thus, expansion of the CED for cochlear implants could result in improved cognition along with improved hearing for many CMS beneficiaries.

Again, we want to thank CMS for your willingness to open the Cochlear Implant NCD for Reconsideration. We appreciate the opportunity to again express the importance of expanding coverage to include patients with sentence recognition scores up to and including 60%. This will not only bring Medicare indications in-line with those of the FDA and many private insurers, but will likely facilitate numerous other positive outcomes for CMS beneficiaries.

We look forward to hearing from you regarding next steps upon completion of the public comment period.

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References


