

**Comments of American Cochlear Implant Alliance (ACI Alliance) regarding the
NCD Reconsideration on the National Coverage Determination for Cochlear Implantation
March 27, 2022**

This NCD Reconsideration was initiated following a request to CMS by American Cochlear Implant Alliance. It was published in the Federal Register (Vol 78, No. 152) on August 7, 2013. The request sought an expansion of cochlear implant (CI) guidelines for Medicare beneficiaries reflecting the experience of the clinician community with the important benefits of cochlear implants (CI) for older adults who have limited ability to understand speech—even using hearing aids. CI centers as well as other hearing care facilities and adults with hearing loss from across the US urged ACI Alliance to: (1) examine and document CI benefits in the population of older adults who might have improved outcomes with earlier access to CI and (2) encourage expanded Medicare candidacy.

Specifically, there was a desire to evaluate benefits for adults 65 years of age or older whose test scores for recorded sentences ranged from 40-60% in the best aided condition, criteria that have been included in Part 2 of CMS Nationally covered indications since April 2005, which states this is possible when providers “are 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.” Additionally, sentence scores less than 60% are similar to those approved by the FDA for commercially available devices, without any specification regarding patient age. A CMS-sponsored study facilitated the examination and documentation of outcomes in a rigorous prospective review involving patients not eligible for CI under Medicare because of obtained scores that fell in the 40-60% range.

Now that the study has been completed and an NCD process is underway, we are pleased at the opportunity to provide comments on behalf of the broad CI clinician and patient communities. The comments provided here summarize the feedback from our multidisciplinary clinician members as well as from those individuals with hearing loss who are potential beneficiaries of a possible expansion in Medicare candidacy criteria. We hear frequently of the frustration and limitations faced by adults who have limited benefit from hearing aids but whose tests scores are considered “too good” for Medicare candidacy.

CMS notes in the NCD announcement that it especially encourages submission of published data on CI outcomes for older adults (outside of the sponsored study) in which candidacy is similar to that of the individuals who participated in the CMS sponsored study. However, given that CI insurance coverage for adults 65 and older is primarily provided through Medicare, such data is lacking as most patients 65 years of age and older are enrolled in Medicare and enrollment in such studies is greatly limited.

The comments submitted here from ACI Alliance summarize findings in this older adult population regarding the impacts of cochlear implantation on improved speech understanding relative to *associated impacts on quality of life and general health, including cognitive status*. We share findings relative to the broad life benefits that access to sound provided by cochlear implants provides to older adults.

Functional Health Outcomes: Cognition

In the past ten years, increasing attention has been focused on the impact of untreated or undertreated hearing loss on the functional health status of older adults, including effects associated with cognition. Research conducted by Frank Lin and others found that individuals with untreated mild, moderate, and severe hearing loss had, respectively, a two-fold, three-fold, and five-fold increased risk of dementia compared with individuals with normal hearing (Lin, *Cerebrum*, 2020). Research suggests that early auditory rehabilitation is important for people of all ages, including older adults, as it can provide benefits and improvements beyond hearing ability such as cognitive function and mitigation of depression. Lin and others studied the impact of rehabilitation with hearing aids and the association with cognitive benefit in older adults (Sarant et al., 2020; Tai et al., 2021; Maharani et al., 2018). CMS beneficiaries who would benefit from the requested reconsideration of the current NCD include those with moderate and severe hearing loss. Based on the research described above, these beneficiaries are at risk for a three- to five-fold increased risk of dementia associated with their hearing loss—a risk that may be mitigated via intervention with a cochlear implant.

Recent studies have examined the impact of cochlear implantation on cognition in older adults. A clinical investigation by Mosnier et al. (2018) analyzed long-term cognitive status and function after CI in 70 individuals 65 and older who qualified for cochlear implants. Cognitive testing was performed before and after CI (after year 1 and after 5 or more years). Mild cognitive impairment (MCI) was observed in 45% of patients *before CI*. Post CI, there was a low rate of progression to dementia and cognitive function improved to normal in 32% of individuals with MCI at the time of CI. The study concluded that cochlear implantation should be routinely discussed as having a possible positive effect on cognitive function in older adults with severe to profound hearing loss who are not sufficiently helped with hearing aids.

A study of cognitive function in adults who received cochlear implants (Zhan et al., 2019) assessed working memory, concentration, inhibition control, and nonverbal reasoning after 6 months of CI use. The study supported the premise that CI may lead to improvements in some cognitive domains.

Functional Health Status of Older Adults

To assess the impact of CI on functional health status of older adults, 47 adults aged 50 and older were studied before and after cochlear implantation. Improvements in health and emotional well-being were associated with increases in speech perception at 6 months and one year post device activation (Francis et al., *Laryngoscope*, 2009). A favorable cost-utility of \$9530 per QALY was found with improvements in speech perception and emotional health.

Quality of Life (QoL)

The World Health Organization defines quality of life as “individuals’ perceptions of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns” (1998). Consideration of quality of life as an important outcome of hearing rehabilitation is increasingly recognized as a key reason for improving access to appropriate hearing technology for individuals of all ages. Making cochlear implantation available to older adults who can benefit from improved access to spoken language and environmental sounds should be recognized as an opportunity to improve overall quality of life.

Two studies conducted in Germany explored health-related quality of life post CI in older adults—patients were 80 and 70 years of age or older (Knopke et al., 2016) and (Olze et al., 2012). Social isolation, disorientation, and quality of life have been described as consequences of severe hearing loss. Both studies explored the impact of CI rehabilitation in older patients beyond improvement in speech perception documenting amelioration of tinnitus, perceived stress, depression, and anxiety.

A systematic review of quality-of-life assessments performed before and after CI (Andries et al., 2021) examined 18 articles that demonstrated significant positive effects of CI on QoL in adults aged 50 and older. An improvement of health related QoL was generally reported when using disease-specific instruments designed to detect treatment-specific changes. The review found assessments of *general* health states were somewhat ambiguous largely because a variety of methods and instruments were used across the studies.

A study involving 371 participants from 20 US cochlear implant centers (McRackan et al., 2019) examined the association of demographic and CI-related factors with quality of life. The study found that age did not impact QoL outcomes demonstrating that data from other studies on CI patients from younger demographics could be applied to Medicare beneficiaries.

In the CMS sponsored study related to this NCD reconsideration, Zwolan et al. (2020) administered the Abbreviated Profile of Hearing Aid Benefit (Cox & Alexander, 1995) and the HUI-3 (BMC/NIH, 2003). The HUI included assessment of 8 different aspects of health utility along with a combined score summarizing all subsections. Analyses revealed statistically significant and clinically important changes in the domains of hearing dexterity and significant change in the HUI-3 Multi score. These findings, reported for patients who received a CI using the guidelines under consideration, indicate that CMS beneficiaries demonstrated significant improvements in several aspects of self-reported quality of life.

Thank you for your consideration of these findings in your decision-making on the National Coverage Determination for Cochlear Implants.

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