

Expanded Medicare Coverage for Cochlear Implants Improves Access

BY DONNA L. SORKIN AND LAURA ODATO

Medicare began covering cochlear implants (CIs) for eligible adults in 1986. The decision to cover was supported by a detailed report from the Office of Health Technology Assessment of scientific and clinical evidence that documented benefits related to restoration of sound detection, improved speech and lipreading and open-set speech recognition, also known as understanding without lipreading for some recipients. Medicare coverage was critical to obtaining access, not only for older adults seeking a CI but also for the impact that it had on coverage for people of all ages with insurance coverage other than that provided by Medicare. In 2005, candidacy criteria were expanded to include adults with more residual hearing (up to 40% of words in sentences) in best-aided condition. This was an improvement, but by the time the expansion occurred, Medicare rules for CI were already more restrictive than the Food and Drug Administration's (FDA) guideline, which is typically followed by private health insurance plans.

On September 26, 2022, the Centers for Medicare & Medicaid Services (CMS) published details on its decision to expand coverage for cochlear implants under Medicare. CMS is the federal agency within the U.S. Department of Health and Human Services responsible for administering the Medicare program. It also works in partnership with state governments to administer Medicaid and other health-related programs. This policy change in coverage criteria was effective the day it was announced. It is notable because the change provides a significant improvement in access to cochlear implant care for older adults who are Medicare beneficiaries. Most U.S. residents who are aged 65 or older rely on Medicare for health care benefits. The broadened criteria bring older adults using Medicare closer to the CI insurance criteria used by most employers and other insurance plans.

The more restrictive candidacy criteria under Medicare, that were in place until recently, hampered CI access for older adults for more than 10 years. Addressing and resolving this issue was an organizational priority for the American Cochlear Implant Alliance (ACI Alliance), HLAA

and people with hearing loss in general. Collaborating with consumer and professional organizations has helped drive our progress to address this inequity in coverage.

Following is a history of this change, what it took to make it and what it means for adults who are covered by Medicare and may benefit from CIs.

ACI Alliance and HLAA Step Up to Advocate for Change

One of the first initiatives undertaken by the newly organized ACI Alliance when it was created in 2011 was conducting a Coverage with Evidence Development (CED) study to explore outcomes in older adults with greater speech recognition than that allowed by then-current Medicare criteria. Principal investigators Teresa A. Zwolan, Ph.D., Craig Buchman, M.D., and John Niparko, M.D., led the multicenter study effort. Studies on CI demonstrated important quality-of-life and related health benefits, including an association between undertreated hearing loss and dementia. It was approved by CMS in 2014, and ACI Alliance moved forward.

HLAA joined CI clinicians in supporting the need for a change in the Medicare criteria. In 2016, Teresa A. Zwolan, an audiologist and then director of the University of Michigan CI Program, and Donna L. Sorkin, executive director of the ACI Alliance and an early CI recipient, presented a workshop at the HLAA Convention in Washington, D.C. They shared information about the study that was underway and encouraged attendees to help spread the word about the need for study participants. CMS had agreed to cover the CI surgery, device and related services for appropriate individuals who met the study criteria, which were more expansive than what was then allowed for those covered by Medicare. Several workshop attendees noted that they had been turned down for a Medicare-funded CI because they had too much residual hearing to qualify, despite having great difficulty hearing in many environments. They were eager to be evaluated for their suitability for the study and let others know of the important opportunity to participate.

Groundbreaking Collaboration Results in Expanded CI Coverage

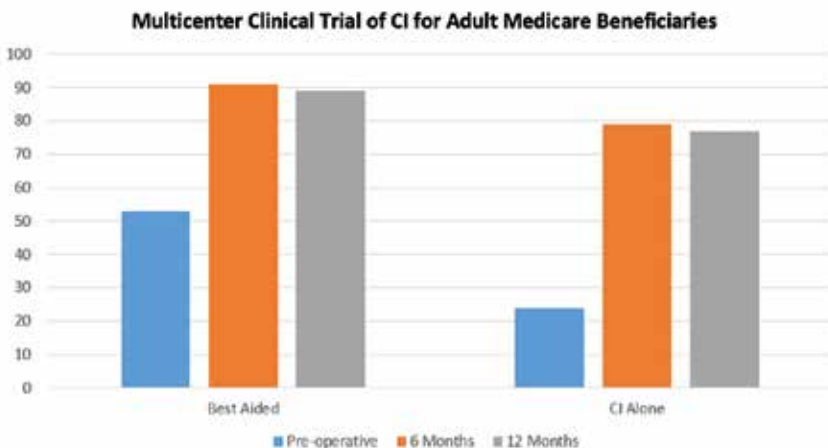
The multicenter study, a collaboration with CMS, was designed to evaluate the safety and efficacy of cochlear implants for Medicare beneficiaries who had more residual hearing than was allowed by Medicare guidelines at the time. The CED study was submitted to CMS in a formal process by which we could initiate consideration of a coverage expansion. The study evaluated cochlear implants for Medicare beneficiaries with preoperative sentence test scores greater than 40%, the candidacy threshold at that time, and up to 60% correct in best-aided condition and were thus wearing well-fitted hearing aids.

Results were published in the respected medical journal JAMA Otolaryngology-Head & Neck Surgery in October 2020. Findings supported the benefits of implantation in this patient population and were submitted as a part of a request for a National Coverage Determination (NCD) under the Social Security Act aimed at expanding Medicare indications for a cochlear implant.

The chart above summarizes the CED study outcomes. Thirty-four Medicare beneficiaries (median age 73.6 years with a range of 65.7-85.1 years) had a median duration of deafness of nearly 11 years. Their baseline, or preoperative-CI sentence discrimination scores, wearing well-fitted hearing aids, were 53% in bilateral condition and 24% in-the-ear to be implanted. At 12 months post-CI, sentence scores in best-aided condition, that typically a CI on one side and hearing aid on the other, was 89% and for CI alone was 77%. Participants experienced a median change in best-aided or bilateral condition and CI alone of 36% and 53%, respectively. These changes were statistically significant and noteworthy, not only for the improvements in speech perception but also for other quality-of-life metrics. The CI provided to this group of older adults changed their hearing profile dramatically, although they received it only because they were part of the CMS-approved study.

Ann Participates in the CED Study and Receives a CI

There was long-running frustration on the part of older adults with hearing loss who didn't qualify for a CI under



Measure	Baseline Median (Min-Max)	6-month Assessment Median (Min-Max)	12-month Assessment Median (Min-Max)
AZ BIO SCORE BEST AIDED	53 (26 to 60)	91 (25 to 100)	89 (36 to 100)
AZ BIO SCORE CI ONLY	24 (0 to 53)	79 (0 to 99)	77 (13 to 100)

Zwolan, Teresa A., Ph.D., et al. "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 Otolaryngology Head and Neck Surgery, Vol. 146, Number 10, Oct. 2020, p. 1-9.

Medicare but would have qualified had they been seeking a CI under a typical, private-employer insurance plan. Ann Liming was one such individual who first learned about cochlear implantation from her older sister, who was diagnosed with hearing loss while still in high school. Ann has long been an active HLAA Member, participating in the HLAA Lansing Chapter and attending many national and state HLAA Conventions. She witnessed firsthand the life-changing benefits for people she knew at the HLAA meetings she attended. When Ann was initially evaluated for a CI, she didn't qualify, as she had too much hearing under Medicare criteria. It was frustrating to repeatedly be counseled by others that she ought to explore a CI, as it would certainly have helped her, but she had been evaluated and declined.

After visiting a friend who was experiencing a similar disappointment, she decided to return to the CI clinic for reevaluation. Although she still did not qualify under typical Medicare rules, she learned of the Medicare coverage expansion study and was invited to participate. CMS covered her evaluation, device, surgery and follow-up care



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just as it would for any eligible Medicare beneficiary. She was thrilled at the opportunity and joined the study effort at the University of Michigan CI Center.

After Ann received her CI, she followed her clinic's guidance on listening practice, using audiobooks and rehab apps that she believes helped make her CI hearing become her new normal. She listens with a CI on one side and a hearing aid on the contralateral ear and is currently considering a second CI.

Ann shared that her CI is very visible, given the fact that she has short hair, and she finds that it's a conversation starter in stores and around town. She always advises that if someone needs a CI and qualifies for one, they mustn't put it off. She is grateful to share her story because she feels that her CI has been a gift to her.

If at First You Don't Succeed, Try Again

The expanded Medicare policy for CI coverage has the potential to be life-changing for many older adults with moderate-to-profound hearing loss who struggle to hear with hearing aids. Patients who have been previously evaluated and told that they did not qualify may wish to go back to a CI center for reevaluation, as they may now qualify under the 2022 criteria. And for those who struggle and have never thought to move forward with a CI, now is a great time to consider this option for better hearing. There are many CI clinics around the country; a listing of active centers may be found at bit.ly/3CAS6q4.

One of the reasons some individuals hesitate to move forward is a fear of losing the hearing they have. The CI surgery has changed, and much of the

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time surgeons are able to preserve residual hearing. Additionally, a careful evaluation helps ensure that most patients gain far more than they lose with the surgery. The 34 older adults who participated in the study had more hearing than was previously allowed under Medicare and they experienced a median change in best-aided or bilateral condition and CI alone of 36% and 53%, respectively. This improvement made a dramatic positive change in their lives.

ACI Alliance offers consumer focused resources on cochlear implants, developed by respected clinicians in the field, and now our focus also encompasses growing awareness of this recent Medicare expansion and the ways it can benefit people with hearing loss. ACI Alliance is working to build partnerships to increase understanding of cochlear implantation. We invite you, members of HLA, to help us enhance awareness of CI candidacy and outcomes. **HL**

Donna L. Sorkin, M.A., is executive director of American Cochlear Implant Alliance, a national organization devoted to expanding access to cochlear implantation for all who may benefit. She hears with a cochlear implant and has had a long career in advocacy for people with hearing loss at nonprofits, including as former executive director of HLA and for-profit entities. She has served on federal, corporate and university boards, including the U.S. Access Board as a presidential appointee, the National Institute on Deafness and Other Communication Disorders at the National Institutes of Health Advisory Board and the Gallaudet University Advisory Board.



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