



AMERICAN ACADEMY OF
OTOLARYNGOLOGY-
HEAD AND NECK SURGERY®

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

Dear Ms. Jensen:

The American Academy of Audiology and the American Academy of Otolaryngology-Head and Neck Surgery appreciate the opportunity to comment on the proposed expansion of the National Coverage Determination policy for cochlear implantation (CI). The American Academy of Audiology is the largest organization in the nation of, by, and for audiologists. We are dedicated to the provision of quality hearing and balance care services through professional development, education, research, and increased public awareness of hearing and balance disorders. The American Academy of Otolaryngology-Head and Neck Surgery is one of the world's largest organizations representing 13,000 specialists who treat the ears, nose, throat, and related structures of the head and neck. We engage our members and help them achieve excellence and provide high-quality, evidence-informed, and equitable ear, nose, and throat care through professional and public education, research, and health policy advocacy.

We are writing in support of the proposed expansion of coverage for cochlear implantation (CI) for adults with aided sentence recognition scores of up to 60% (an increase from 40%). CI is a well-established, non-experimental intervention that is appropriate for adults, including Medicare beneficiaries, who receive limited benefit from hearing aids. CIs have been approved by the FDA since the mid-1980s. We submit our comments in collaboration for two reasons: first, in recognition of the necessary collaboration that exists in any cochlear implant program that achieves positive outcomes for their recipients, and second, in representation of our mutual support for the expansion of cochlear implant candidacy for Medicare beneficiaries that is in the best interest of our shared patients.

Our comments herein offer evidence in support of our recommendation to expand current coverage guidelines for CI. Specifically, we focus on three topics that are most salient to our recommendation: (1) clinical best practices, (2) disadvantage of current Medicare coverage policy for beneficiaries relative to other insurance programs, and (3) reported outcomes in patients with pre-operative aided speech recognition $\geq 40\%$ and $\leq 60\%$.

Clinical Best Practices

Since the earliest recipients received their devices more than 40 years ago, CI has continued to evolve, benefiting more individuals with greater diversity of hearing loss. Originally introduced for those with bilateral profound sensorineural hearing loss, cochlear implants were considered a last resort when hearing aids could no longer provide adequate benefit. Today this perspective is considered woefully outdated. Cochlear implantation has been shown to be a reliable intervention across the lifespan for the majority of adults who have limited speech perception abilities, with average post-operative speech recognition of 54% (words), 74% (sentences), and 50% (speech in noise) (Boisvert et al, 2020). More recently, Holden et al (2013) and Buckman et al (2020) have confirmed this with mean CNC word scores of 62%. Notably, research suggests that earlier implantation with less severe degrees of hearing loss and more measurable residual hearing results in higher post-implant speech recognition scores (Dowell, 2016; Birman & Sanli, 2020; Quatre et al, 2020; Holden et al, 2013) and improved quality of life (Quatre et

al, 2020). Successful recipients include those with single-sided deafness (Arndt et al, 2011; Galvin et al, 2019; Jakob et al, 2021), asymmetric hearing loss (Firszt et al, 2018), residual hearing in the implanted ear up to and including normal low frequency thresholds through 1000 Hz (Gantz et al, 2016; Dunn et al, 2020), and sudden loss (Shearer et al, 2017; Bernhard et al, 2021). Candidacy determination is shifting from the use of sentences in quiet in the best-aided condition to ear-specific word recognition scores (Gifford et al, 2010; Sladen et al, 2017). Electric-acoustic stimulation in the same ear is possible (Gantz et al, 2022).

Despite these advancements, a recent study by Nassiri, Sorkin, and Carlson (2022) suggested that more than an estimated 1 million patients who could benefit from CI have failed to receive one. Only 12.7% of US adults who met traditional audiometric CI candidacy criteria (i.e., postlingual onset of bilateral severe-to-profound sensorineural hearing loss [>70 dB HL], minimal-to-no benefit from appropriately fitted hearing aids defined by meeting FDA labeled criteria [$<50\%$ ipsilateral sentence recognition in quiet and $<60\%$ contralateral sentence recognition in quiet]) received a cochlear implant, leaving over 87% to struggle unnecessarily.

Importantly, auditory rehabilitation by cochlear implants has been shown to be effective among older adults (>65 years; median age 74 years) with different degrees of hearing loss, and enables positive improvements in terms of social isolation, depression and cognitive performance (Castiglione et al, 2016; Gurgel et al, 2022). Specifically, Wick et al (2020) conducted a subgroup analysis of patients 65 years or older enrolled in a within-subject clinical trial of cochlear implantation. They demonstrated clinically meaningful improvement on both word recognition and quality of life benefit with an acceptable risk profile, suggesting that cochlear implantation in older adults may facilitate the concept of healthy aging.

Furthermore, the frailty index does not correlate with hearing scores after cochlear implantation in recipients aged ≥ 65 years. A lower frailty index and a greater improvement in hearing thresholds do predict better quality of life scores (Aylward et al, 2021), which should encourage pursuing cochlear implantation at the earliest possibility instead of waiting for hearing to decline to a more severe threshold.

Better pre-operative hearing thresholds are associated with better post-operative outcomes in pre-lingually deafened adults (American Academy of Audiology). Although older and younger adults with implants achieve the same magnitude of pre- to post-implant speech recognition benefit in quiet, the overall postoperative speech recognition outcomes in quiet and noise are superior in younger compared to older adults. Cochlear health is considered the most significant factor for post-operative speech perception. Prolonged duration of severe-profound deafness which may result in deterioration of cochlear structures, has also been consistently shown to be a significant predictor of post-operative outcomes (Bernhard, 2021). Both of these speak to the value of earlier implantation to achieve maximal results.

Although clinical best practices dictate offering cochlear implantation to patients earlier and with greater degrees of residual hearing, clinicians are often limited in the ability to do so by coverage policies of payers that do not align with rapidly advancing research findings. Access to CI is most limited for Medicare beneficiaries due to coverage policies which are more restrictive than current clinical practice, or even FDA labeling. Current CMS coverage policies require patients to wait until their hearing loss is more severe, which can limit optimal outcomes.

Disadvantages of Current Coverage Policy

The current Medicare coverage policy significantly disadvantages existing and future beneficiaries with less severe hearing loss from receiving cochlear implantation despite evidence that earlier intervention can positively affect cognitive decline progressive neurologic disorders, depression and overall quality of life for these patients. Appropriate early intervention with cochlear implantation in properly selected patients has significant potential to lower overall costs of healthcare for these individuals as well as improving quality of life. Projections indicate that the 64 million adults (20% of the U.S. population) currently enrolled in Medicare will increase to 92.4 million by 2050 (Congressional Research Service;

Kaiser Family Foundation). It makes both societal and economic sense to make Medicare benefits available to these individuals if they choose to use them.

Despite this rapidly increasing need, CMS has adopted more restrictive criteria for cochlear implantation compared to private insurance companies, including Medicare Advantage (Medicare Part C) plans. For adults, cochlear implant manufacturers have labeled pre-operative sentence recognition scores no better than 60% in the better hearing ear and when bilaterally aided. Similarly, military personnel and veterans receiving cochlear implants within the Department of Defense or Veterans Affairs Medical Center health care systems also receive CIs based on FDA guidelines (VHA and DoD 2017). FDA guidelines have been evolving and expanding in the last several years, as evidenced by recent premarket approvals (FDA 2014; 2019, Cochlear, 2020), though these expanding FDA criteria and private insurance coverage are not expanding quickly enough to keep up with clinical best practice (Zwolan & Basura, 2021; Moses & Friedmann, 2021). Although many commercial plans list FDA labeling as their coverage policy, nearly all allow preauthorization and may approve CIs even if outside of traditional Medicare requirements or FDA labeling (e.g., Zwolan & Basura, 2021). Medicare Part B beneficiaries are not eligible for special consideration, placing them at a significant disadvantage compared to their peers due to much more restrictive criteria and rigid policies. This access disadvantage is quantifiable; patients with military insurance were 13 times more likely to pursue surgery as compared to patients with Medicare (OR 13.0; 95% CI: 1.67-101.4) (Tolisano et al, 2019).

Despite expanding FDA indications and evolving evidence-based clinical practices, CMS criteria has not changed since 2005. Moreover, the current inclusion criteria require preoperative sentence recognition scores no better than 40%. This effectively eliminates the many patients who score up to 60% that have been shown in many studies to benefit from cochlear implantation from having access to them. The proposed coverage expansion would bring Medicare coverage more in-line with FDA labeling and would create access to this life-changing technology for Medicare beneficiaries that is more on par with their non-Medicare Part B peers.

The current coverage discrepancy for Medicare Part B beneficiaries has limited the ability to quantify the benefit of CI in patient cohorts over age 65 covered by Part B Medicare with pre-operative sentence recognition >40% because these patients can only currently be implanted as part of a clinical trial, unlike their non-Medicare Part B counterparts.

Clinical Outcomes with Expanded Pre-Operative Word Recognition Scores

In the last three years, several studies have specifically considered outcomes for patients with sentence recognition scores >40% and <60%; the results of which support implantation of candidates with greater degrees of pre-operative sentence recognition ability than is currently covered under CMS guidelines.

Study #1. A group of older adults with average age of 73.26 years old and average preoperative sentence recognition scores in quiet of 47% in the ear to be implanted showed significant improvements with their CI, with an average of 72% scores post-operative. Even in the bilateral hearing condition, pre-operatively, although they scored 70% in quiet, overall postoperative results found that patients' hearing improved for every test condition, including 12% improvement in the bilateral condition and 24% average improvement in the ear to be implanted, reinforcing that even for patients scoring >40% on sentences in the pre-operative condition, not only does CI not worsen their performance, but it reliably improves it (Mudery et al, 2017).

Study #2. Zhang & Coelho (2018) showed mean postoperative sentence recognition scores in quiet of 90% for older patients who had preoperative sentence recognition > 40% in quiet. Patients were divided into three groups depending on the variable preoperative testing conditions. Group 1 consisted of patients who met CMS CI criteria in quiet for both sentence recognition and monosyllabic word recognition (AzBio quiet <40%, CNC quiet <40%). Group 2 consisted of patients who did not meet CMS CI criteria in sentence recognition in quiet but had sentence recognition of <40% in noise (+5 dB SNR) (AzBio quiet

>40%, AzBio noise < 40%). Group 3 consisted of patients who had sentence recognition <40% in noise and had poor monosyllabic word recognition (CNC) in quiet (AzBio quiet >40, AzBio noise 40, CNC quiet < 40%). All three groups received statistically significant benefit from their cochlear implant as measured by both postoperative sentence and word recognition. For sentence recognition, Group 1 had a mean postoperative AzBio score (quiet) of 83.1% (SD = 17.4%, p<0.01), Group 2 had a mean postoperative AzBio (quiet) score of 90.1% (SD = 7.9%, p<0.01), and Group 3 had a mean postoperative AzBio (quiet) score of 90.6% (SD = 6.9%, p<0.01).

Study #3. Zwolan et al (2020) evaluated pre- and post-operative speech perception scores in 34 adults over 65 years of age. Sentence recognition scores tested prior to receiving a cochlear implant fell between 41% and 60%, outside of the current CMS criteria. After one year of cochlear implant use, speech perception testing revealed a median improvement of 36% in the best-aided condition and a 53% improvement for the cochlear implant alone listening condition. These results deliver compelling evidence of the clear benefits of cochlear implantation in this population, with median post-operative best aided scores of 89% and cochlear-implant only scores of 77%.

In summary, we endorse those policies that encourage access to best practices that have been shown to deliver best outcomes. Therefore, we unreservedly recommend the expansion of Medicare coverage to include those cochlear implant candidates with best aided sentence recognition scores up to 60%.

Sincerely,



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