Why Does Medicare Cover Cochlear Implants But Not Hearing Aids?

By Fan-Gang Zeng, PhD

A growing body of scientific evidence shows that hearing loss not only limits acoustic sensations and speech comprehension, especially in noisy environments, but it also impairs quality of life and even socioeconomic status. While cochlear implants and hearing aids can ameliorate the effects of hearing loss, the medical coverage levels of these devices are vastly different in the United States.

Medicare, the federal health insurance program for 50 million elderly (≥65 years old) and 7 million disabled Americans under 65, paid a total benefit of $606 billion in 2015, accounting for 15 percent of the federal budget. Currently, Medicare pays approximately a national average of $24,000 for a cochlear implant, but $0 for hearing aids (Table 1). Let’s examine this coverage disparity from scientific, regulatory, and political viewpoints.

First, to be covered by Medicare, a device must provide a health benefit and “be determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member” (Social Security Act).

As early as October 1986, cochlear implants, both 3M/House single-channel and Nucleus-22 devices, were covered for adult Medicare beneficiaries. This was supported by a 44-page report on scientific and clinical evidence from the Office of Health Technology Assessment (OHTA), a federal agency that made Medicare policy recommendations at the time (Feigenbaum. NCHSR, 1986). The 1986 report determined that cochlear implants restored sound detection, improved voice modulation and lip-reading, and, in some patients, provided a considerable degree of open-set speech recognition.

In 1992, Medicare coverage of the cochlear implant was extended to children. In 2005, the Centers for Medicare and Medicaid Services (CMS) markedly expanded the audiological criterion to include individuals who received a pre-implant score of ≤40 percent open-set sentence recognition under the best-aided listening condition (CAG-00107N).

Today, Medicare not only covers the cochlear implant, but also its accessories such as microphones and batteries. The surgery may include additional coverage from the use of operating microscope to intra-surgical monitoring.

The OHTA and CMS guidelines relied heavily on peer-reviewed publications; to a lesser extent, on data submitted by the manufacturers to the Food & Drug Administration (FDA) and on professional society position statements; and the least extent, on expert opinions. For example, the CMS responded to three commentators who provided solid but unpublished data that they “encourage parties with such data to pursue publication, and thereby enlarge the pool of published evidence.” Apparently, the CMS has determined that the published evidence on the health benefits of hearing aids is inadequate, and that, accordingly, hearing aids do not merit any coverage.

Second, regulatory differences contribute to the coverage disparity. The cochlear implant, as a Class-III medical device, has to be proven both safe and effective through comprehensive and expensive clinical trials required to obtain FDA approval. Most hearing aids are regulated as a low-risk Class-I device, and generally exempt from FDA review and clearance before marketing. Bone conduction hearing aids and tinnitus

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Table 1. Medicare Coverage of Cochlear Implants and Hearing Aids

<table>
<thead>
<tr>
<th>Medicare coverage (US$)</th>
<th>Cochlear implants (CPT)</th>
<th>Hearing aids (CPT)</th>
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<tbody>
<tr>
<td>Device</td>
<td>22006.33 (L8614)</td>
<td>0 (V5030-V5336)</td>
</tr>
<tr>
<td>Surgery</td>
<td>1268.55 (69930)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Programming</td>
<td>143.22 (92601, 92603)</td>
<td>0 (92591-92595)</td>
</tr>
<tr>
<td>Rehabilitation (per hour)</td>
<td>90.58 (92602, 92604, 92627)</td>
<td>0 (92630, 92633)</td>
</tr>
</tbody>
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CPT: Current Procedural Terminology codes are the most widely accepted medical language used to report medical procedures and services under public and private health insurance programs (www.cms.gov).
maskers are regulated as Class-II devices and may gain FDA clearance before marketing by simply demonstrating their equivalence to an existing product without conducting any clinical trials. While the exemption or clearance regulation has shortened the time to market for hearing aids, the lack of prospective randomized controlled clinical trials to demonstrate its health benefits prevents Medicare coverage of these devices. Ultimately, achieving Medicare coverage of hearing aids and determining criteria and extent of coverage will depend on the willingness and ability of hearing aid manufacturers to quantify the health benefits of hearing aids, which would be directly compared to other covered medical devices.

Finally, cochlear implants require a surgery performed by physicians, and pre- and post-surgical evaluation and programming by audiologists. The relationship between the physician and audiologist is interdependent and collaborative. In contrast, hearing aid fitting does not require any surgery and hearing aids are dispensed by audiologists or specialists—a process that seldom engages physicians. The CMS is primarily composed of physicians who decide on what to cover as well as how much to cover (Pear. New York Times 2015). In my opinion, this lack of an organic relationship between hearing aid dispensers and physicians has led to the present coverage disparity between cochlear implants and hearing aids.