

VII. Scope of Hearing Aid Coverage Exclusion

A. Background

Section 1862(a)(7) of the Act states notwithstanding any other provision of title XVIII, no payment may be made under part A or part B for any expenses incurred for items or services “where such expenses are for . . . hearing aids or examinations therefor. . . .” This policy is codified in the regulation at 42 CFR 411.15(d), which specifically states that hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids are excluded from Medicare coverage. At the time of passage of the Social Security Amendments of 1965 (Public Law 97, 89th Congress), which added the Medicare coverage exclusion for hearing aids at section 1862(a)(7) of the Act, all hearing aids utilized functional air and/or bone conduction pathways to facilitate hearing.

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In general, to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. With regard to section 1862(a)(7) of the Act, we consider that a hearing aid provides assistance or "aid" to hearing that already exists via a functioning ear. Cochlear implants were the first hearing device that was not considered a hearing aid and met the benefit category of a prosthetic device. Prosthetic devices are a Medicare benefit category defined at section 1861(s)(8) of the Act which, in part, states a "prosthetic devices (other than dental) which replace all or part of an internal body organ." A cochlear implant is considered a prosthetic device primarily because it replaces the function of the cochlea. A cochlear implant device differs from a hearing aid in that it is an electronic instrument, part of which is implanted surgically to directly stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze and code sound. Both cochlear devices and brain stem implants, which function in a similar manner, create the perception of sound rather than aid hearing that already exists. We interpret the statute as excluding devices that provide aid to extant hearing (or hearing aids) rather than devices that create the perception of sound and hearing, given that devices with technology that utilize either air or bone conduction via mechanical stimulation to aid extant hearing were primarily utilized when the statute was written. Moreover, we believe that

prosthetic hearing devices are not “hearing aids” given that such devices do more than “aid” in hearing and instead replace the function of an internal body organ (i.e., a part of the ear).

Historically, CMS has periodically addressed the scope of the Medicare hearing aid coverage exclusion through program instructions and national coverage policies or determinations. We briefly discuss the relevant changes that have occurred over time with regard to Medicare coverage and payment of hearing devices.

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Cochlear implants were the first device covered for Medicare payment for adult beneficiaries in October 1986, when no other hearing device was being covered under Medicare, and such coverage was supported by the Office of Health Technology Assessment’s “Public Health Service Assessment of Cochlear Implant Devices for the Profoundly Hearing Impaired”, dated June 30, 1986 found at

https://archive.org/stream/cochlearimplantd00feig/cochlearimplantd00feig_djvu.txt. Medicare coverage was restricted to cochlear implants that treated patients with post lingual, profound, bilateral, sensorineural deafness who are stimuable and who lack the unaided residual auditory ability to detect sound.

Effective January 1, 2003, we clarified that the hearing aid exclusion broadly applied to all hearing aids that utilized functional air and/or bone conduction pathways to facilitate hearing (see section 15903, Hearing Aid Exclusion, Medicare Carriers Manual, Part 3 – Claims Process (HCFA-Pub. 14-3), which was later moved to section 100, Hearing Aids and Cochlear Implants, of Chapter 16, of the Medicare Benefit Policy Manual, CMS-Pub. 100-02). Any device that does not produce at its output an electrical signal that directly stimulates the auditory nerve is a hearing aid for purposes of coverage under Medicare. Devices that produce air conduction sound into the external auditory canal, devices that produce sound by mechanically vibrating bone, or devices that produce sound by vibrating the cochlear fluid through stimulation of the round window are considered hearing aids and excluded from Medicare coverage.

Effective April 4, 2005, Medicare's national coverage policy for cochlear implants was modified through the NCD process (see section 65-14 of the Medicare Coverage Issues Manual

findings under the NCD, in part, state that "CMS has determined that cochlear implants fall within the benefit category of prosthetic devices under section 1861(s)(8) of the Social Security Act." Medicare is a defined benefit program. An item or device must not be statutorily excluded and fall within a benefit category as a prerequisite to Medicare coverage. We believe that prosthetic hearing devices are not "hearing aids" given that such devices do more than "aid" in hearing and instead replace the function of an internal body organ (i.e., a part of the ear). Additional changes, regarding coverage criteria, have been made to NCD 50.3 over time, however, the NCD decision regarding benefit category and Medicare coverage for cochlear implantation has remained consistent. The NCD states that a cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

The regulations at 42 CFR §419.66 were revised to add new requirements, effective January 1, 2006, for transitional pass-through payments for medical devices. The auditory osseointegrated device, referred to as a bone anchored hearing aid (BAHA), was determined to be a new device category according to the new requirements for transitional pass-through payment. Medicare coverage was also expanded to cover auditory osseointegrated and auditory brainstem devices as prosthetic devices. Currently, section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) reads as follows:

Hearing aids are amplifying devices that compensate for impaired hearing.

Hearing aids include air conduction devices that provide acoustic energy to the cochlea

via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

Certain devices that produce perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve are payable by Medicare as prosthetic devices.

These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.

The following are considered prosthetic devices:

- Cochlear implants and auditory brainstem implants, that is, devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.
- Osseointegrated implants, that is, devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer.

B. Current Issues

We have received several benefit category determination requests in recent years for the consideration of non-implanted, bone conduction hearing aid devices for single-sided deafness, as prosthetic devices under the Medicare benefit. We have received similar requests for several other types of implanted and non-implanted devices as well. In response to these requests, we have re-examined the scope of the statutory hearing aid exclusion. Currently, we consider all air or bone conduction hearing devices, whether external, internal, or implanted, including, but not

limited to, middle ear implants, osseointegrated devices, dental anchored bone conduction devices, and other types of external or non-invasive devices that mechanically stimulate the cochlea, as hearing aids. All of these devices provide traditional "aid" to hearing and are excluded in accordance with section 1862(a)(7) of the Act. In order for an item to be covered by

Medicare, it must fall into a Medicare benefit category and not be statutorily excluded. Not only are these devices statutorily excluded they do not fall in a benefit category. Specifically, they do not meet the statutory definition of a prosthetic device found at section 1861(s)(8) of the Act which, in part, states a "prosthetic devices (other than dental) which replace all or part of an internal body organ." They do not replace the function of an internal body organ and thus are not considered prosthetic devices under Medicare payment policy. In regard to BAHA, it is a bone conduction hearing aid device that is osseointegrated. There are currently only two hearing devices that are not statutorily excluded and are a covered Medicare item that fall into the prosthetic benefit category; namely, the cochlear implant and the auditory brainstem device. These two devices meet the definition of a prosthetic device in that they replace the function of the inner ear consistent with the definition of prosthetic devices described in section 1861(s)(8) of the Act .

C. Proposed Provisions

After further considering the statutory Medicare hearing aid exclusion under section 1862(a)(7) of the Act, and re-examining the different types of external and implanted devices, we propose to interpret the term "hearing aid" to include all types of air or bone conduction hearing aid devices, whether external, internal, or implanted, including, but not limited to, middle ear implants, osseointegrated devices, dental anchored bone conduction devices, and other types of external or non-invasive devices that mechanically stimulate the cochlea. We believe, based on

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our understanding of how such devices function, that such devices are hearing aids that are not otherwise covered as prosthetic devices, in that they do not replace all or part of an internal body organ. Therefore, we propose to modify the regulation at §411.15(d)(1) to specify that the hearing aid exclusion encompasses all types of air conduction and bone conduction hearing aids (external, internal, or implanted). Osseointegrated devices such as the BAHA are bone conduction hearing aids that mechanically stimulate the cochlea; therefore, we believe that the hearing aid exclusion applies to these devices and propose that Medicare should not cover these

devices, consistent with our interpretation of section 1862(a)(7) of the Act. In addition, an NCD was issued for cochlear implant devices with the result that this determination and recent requests to expand coverage of hearing devices raises serious questions about the intent and scope of the Medicare coverage exclusion for hearing aids. It is for these reasons that we are addressing the hearing aid coverage exclusion in notice and comment rulemaking, and believe that the BAHA device qualifies as a hearing aid because it functions like other bone conduction hearing aids that are subject to the Medicare statutory coverage exclusion for hearing aids.

We continue to believe that the hearing aid exclusion does not apply to brain stem implants and cochlear implants because these devices directly stimulate the auditory nerve, replacing the function of the inner ear rather than aiding the conduction of sound as hearing aids do. Therefore, we are not proposing any changes to our current policy about brain stem implants and cochlear implants and how such implants fall outside of the hearing aid statutory exclusion (that is, such devices would fall outside the Medicare coverage exclusion for hearing aids and remain covered subject to the Medicare NCD 50.3 found at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_Part1.pdf). We propose, however, to
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modify § 411.15(d)(2) to specifically note that such devices do not fall within the hearing aid exclusion.

We seek public comment on this proposal.