



AMERICAN ACADEMY OF
OTOLARYNGOLOGY-
HEAD AND NECK SURGERY



September 2, 2014

Marilyn Tavenner, RN
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Attention: CMS-1614-P, P.O. Box 8010
Baltimore, MD 21244-8010

Re: Scope of Hearing Aid Coverage Exclusion in the Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Proposed Rule

Dear Administrator Tavenner:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), American Otological Society (AOS), American Neurotology Society (ANS), we respectfully submit the following comments on the “Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies” published in the *Federal Register* as a proposed notice on July 11, 2014. The proposal to revise the hearing aid exclusion to encompass osseointegrated implants and all other bone conducting auditory prosthetics will have a significant detrimental impact on many *patients*. After reviewing the proposed rule, it seems that there may be a misunderstanding of the physiology of the ear, so we would like to provide a brief overview of the parts of the ear and sound energy pathways involved in hearing. Further, we provide comments on the amplifying effect of the middle ear and why we *strongly disagree* with the proposed rule in the cases of maximal conductive hearing loss, mixed hearing loss, and in unilateral deafness. Finally, we would like to offer a suggestion for CMS to consider as the agency works to finalize the rule so that Medicare beneficiaries who do not benefit from hearing aids and require bone conducting auditory prostheses receive access to care.

I. Impact of Hearing Loss on Patient Safety and Quality of Life

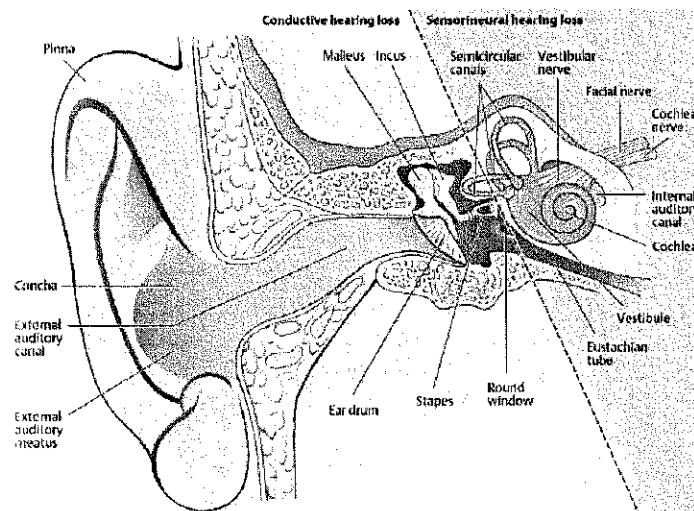
Hearing loss in both ears reduces an individual’s sound awareness and ability to communicate. Unilateral hearing loss impairs an individual’s ability to localize sound and hear in the presence of competing background noise and is both a communication and personal safety issue. In both cases, untreated hearing loss alters a person’s ability to function in day to day listening situations and thus, can negatively impact on employment opportunities, health and safety, and quality of life. Recently, the detrimental effects of

hearing loss in the elderly have been recognized in the areas of physical activity, frailty, health care expenditures, social isolation, depression, cognition, dementia, and even earlier mortality (1-11). Hearing loss is not just an inconvenience, but a significant health condition when untreated.

While hearing loss commonly occurs in the elderly population as a result of aging (i.e. presbycusis or “common, usual or regular hearing loss”), it can also occur as a consequence of medical conditions that effect the ear such as infections, tumors, trauma, developmental, ototoxic (such as side effects from medications), and other disorders. A conductive hearing loss results from dysfunction or absence of the external auditory canal, tympanic membrane (TM or eardrum), and ossicular chain (middle ear bones: malleus, incus, stapes) (yellow area in figure below). Sensorineural hearing loss (often called “nerve deafness”) occurs when cochlear and neural dysfunction exists (Green area in figure below).

II. Anatomy and Physiology Considerations for Prosthetic Hearing Devices

As CMS considers how to define the scope of the hearing aid exclusion, it is important to understand the anatomy and physiology of the ear. The ear is an organ with three parts - the outer ear, the middle ear and the inner ear - two of which are internal to the body (See the figure below).



The outer ear collects acoustic energy (sound waves) from the air, the middle ear focuses and amplifies this acoustic energy and transforms it into mechanical energy (yellow area above). The inner ear receives the amplified mechanical energy at the oval window where it is transformed into hydraulic energy that moves the cochlear fluids. This in turn, activates the hearing receptors (i.e. hair cells) as it moves over them to generate nerve impulses to the brain (green area above). If any part of the system stops functioning, hearing is lost and in order to restore hearing, the non-functioning portion of the ear must be replaced. For example, if one or more of the bones of the middle ear (the ossicles) are

unable to receive and transmit mechanical energy, hearing will be lost because the cochlea requires the highly amplified mechanical energy it receives from the middle ear and responds poorly without it. Depending on what portion of the ear is not working, there may be a number of ways to restore hearing. In some cases, use of a prosthetic device is the most appropriate, and may be the only treatment option. There are several FDA approved prostheses that otolaryngologists use to replace the function of the deaf ear. Some of these devices require surgery while others do not. *The following more detailed review of the anatomy and physiology of the ear is essential to establishing the understanding for why some patients need bone conducting auditory prosthetics as these devices do not provide the same effect as a hearing aid, that a hearing aid would not allow patients who need bone conducting auditory prostheses to be able to hear because these patients are missing a part of the ear, and why CMS should continue to provide coverage for these prostheses.*

The outer ear (pinna and external auditory canal or EAC) and the middle ear (TM, ossicular chain, Eustachian tube (ET) and aerated middle ear space) are essential in the physiology of hearing. Each element provides not only a collecting mechanism, but a measurable and highly significant amplification and transfer function for hearing. Without the amplification and energy transfer capabilities of the outer and middle ear, the cochlea along with the auditory nerve cannot perform the functions that enable hearing. Therefore, any device that replaces any portion of the outer or middle ear improves the "perception" of sound.

More specifically, the middle ear and its structures are not just passive transmitters of sound, but are essential amplifiers, modulators and transformers of acoustical energy as they transmit sound across the air-fluid interface and in to the fluid-filled cochlea. Normally, when airborne vibrations of sound impinge on a fluid surface, more than 99.9% of the sound energy is reflected back from the surface. A properly functioning hearing system overcomes the problem of the air-fluid interface through the functions of the middle and outer ears. Anatomically, the consistency, shape and size of the TM focuses acoustic energy into the middle ear ossicles. The acoustic energy is transformed into mechanical energy at that point and the mechanical energy travels through the ossicles and impinges on the oval window through stapes vibrations, which is the door to the inner ear. The surface area of the oval window is 28 times smaller than the TM. The combination of focusing acoustic energy 28 fold along with the 1.32:1 amplifier effect of the ossicles provides a mechanical advantage that creates a ~30 dB increase in the effectiveness of hearing. Thus, when the TM and middle ear ossicles are absent (with a patent ear canal), there is a loss of approximately 35 dB of the sound transmitted. In other words, if sound entering the ear canal travelled directly to the inner ear via the round window, it would leave a significant hearing loss owing to the lack of the conducting and amplifying mechanism. If one adds to that any additional barriers such as scar tissue from ear infections, atresia (severely narrowed or totally closed ear canal), inflammation, or debris (cerumen, skin), the deficit is even greater. In the worst of instances, if the TM were to be intact without hearing bones (i.e. ossicles), sound energy travelling down the ear canal would be reflected at the TM without delivery to the cochlear partition, thereby imparting a 60 dB hearing loss. The dB scale rating is a logarithmic scale, thus a 60 dB

loss would indicate a relative loss of power 1,000,000 times less than normal hearing at 0 dB. In summary, the combination of an intact, mobile, normally configured TM together with the transformer lever action of the ossicular chain are critical functions of the organ we call the middle ear that enable us to hear. We also note that the Eustachian tube ventilates the middle ear space and must function normally to avoid any pressure differential between the middle ear and inner ear hearing mechanisms and the surrounding environment of sound.

III. Therapeutic Considerations as it Relates to Ear Diseases

In some instances, disease renders the conductive mechanism non-functional and irreparable using medical/surgical restorative approaches (e.g. canalplasty, atresioplasty, tympanoplasty, or ossiculoplasty), thus the individual has permanent hearing loss. In these instances, the external auditory canal may be absent, closed, or severely deformed. Moreover, the TM and ossicular chain may also be unavailable for use or absent. In each case, conventional air conduction hearing aids will be unable to provide sufficient delivery of sound energy to the inner ear for the reasons previously discussed.

Similarly, the sensorineural mechanism (cochlea, auditory nerve and brain) can be damaged from diseases (congenital, traumatic, inflammatory or neoplastic), resulting in significant hearing loss on one side. In such cases, a conventional air conduction hearing aid is unable to provide sufficient sound energy input to the brain for interpretation.

In the former condition (i.e. conductive hearing loss), an option exists to deliver sound energy through the bone of the skull (i.e. bone conduction), bypassing the damaged or deficient ear canal, TM or ossicular chain, to activate the cochlea and restore hearing for these patients. This procedure reestablishes the amplifying and transfer functions that a normal middle ear performs. For the unilateral sensorineural hearing-impaired patients, sound can also be passed through the bone of the skull, to activate the functioning cochlea on the opposite side of the head. In this instance, patients can have better hearing in noise on the deaf ear side. The preferred treatment option for both conductive and unilateral sensorineural hearing loss will vary depending on the patient's anatomy and underlying condition and is best deciphered by the treating physician together with the patient. Importantly, in some patients (e.g., patients with irreparable middle ear damage), the only treatment option will be use of a bone conducting auditory prosthetic.

IV. CMS Proposed Policy Change

"The hearing aid exclusion" statute excludes the coverage for hearing aids. CMS has the latitude to interpret this statute through policy as below:

Section 1862(a)(7) of the Social Security Act states that no payment may be made under part A or B for any expenses incurred for items or services "where such expenses are

for...hearing aids or examinations therefore..." This policy is further reiterated at the 42 CFR 411.15(d) below and included in the proposed rule:

§ 411.15 Particular services excluded from coverage.

(d) Hearing aids or examinations for the purpose of prescribing, fitting, or changing hearing aids

- (1) ***Proposed Rule Scope.*** The scope of the hearing aid exclusion encompasses all types of air conduction and bone conduction hearing aids (external, internal, and implanted).
- (2) ***Devices not subject to the hearing aid exclusion.*** Cochlear Implants and auditory brainstem implants that replace the function of the cochlear structure or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays. These devices produce the perception of sound and do not meet the definition of hearing aid.

Since 2006, the Medicare Benefit Policy Manual definition of hearing aids has been the following:

"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."

CMS policy states: "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."

V. Suggested Alternative to Proposed Rule

In response to the proposed rule, we propose that a hearing aid is an amplifying device that compensates for impaired hearing. Hearing aids include air conduction devices that provide amplified acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include non-osseointegrated bone conduction devices that provide amplified mechanical energy to the cochlea via indiscriminate stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

An osseointegrated implant is clearly a prosthesis, as defined by CMS which is supportable and reasonable. It replaces the missing or non-functional organ or component

of part of the hearing system in the body. It replaces the conductive mechanism of the external auditory canal, TM, and/or ossicular chain in cases where these structures are not available or are non-functional. *These devices are used only when use of a hearing aid is either not possible or has been ineffective in providing adequate auditory information.* Examples of when a hearing aid is not possible include but are not limited to: absent or deformed external ear, pinna, or ear canal; absent or perforated TM; open mastoid cavity; chronic infection; or large or inflamed meatus (opening of the ear canal to the outside world that cannot be fit). Conditions in which a hearing aid is ineffective in providing adequate auditory information could include but are not limited to instances such as a lack of satisfactory gain, intolerable or persistent feedback, non-function of one cochlea, ear canal occlusion, related infection, chronic otorrhea (drainage from the ear, usually infected), edema, chronic dermatitis of the ear canal and/or ear canal opening, and chronic pain related to device retaining bands.

Osseointegrated implantable devices are able to mitigate many or all of these factors that make air conduction or bone conduction hearing aids that are applied indiscriminately to the skin surface unusable. The osseointegrated implant is physically and functionally distinguishable from a bone-conduction hearing aid in that they: (1) are never retained by a headband, and (2) supply focused stimulation to the temporal bone structures through an implant that is physically integrated (osseointegrated) into the bone of the skull. The purpose of the osseointegrated implant is to replace the function of an absent or diseased body part (i.e., a prosthesis). In many instances, these are the only options for hearing restoration for some patients.

The medical literature strongly supports the viability of osseointegrated implants as safe, effective, and cost-effective, for patients (12-109). Osseointegrated implants improve hearing for patients with bilateral conductive hearing loss, mixed hearing losses, and single sided deafness. A recent clinical trial also clearly shows that osseointegration of an implant provides improved patient hearing performance over conventional bone-conduction hearing aid that use only a headband (Reference Note 1).

In addition, from an economic and patient outcomes/safety/satisfaction perspective, for patients that have failed previous surgical attempts at hearing reconstruction using conventional techniques, it potentially makes better sense for Medicare to provide osseointegrated implants for these patients indicated only after careful and thorough evaluation by an otolaryngologist-head & neck surgeon in lieu of repeated, costly traditional surgical attempts without an osseointegrated implant. In other words, the lack of coverage may have the unintended consequence of incentivizing revision surgical encounters. In fact, recent literature looking at the cost of care for such patients suggests an opportunity for cost savings, improved performance and quality of life using a paradigm based on implantable devices. (110).

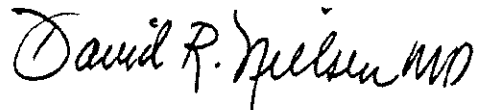
On behalf of our patients, we therefore respectfully request that CMS adhere to carefully crafted and defensible definitions it has followed since 2006 (with minor modification as above), providing needed help to those patients who require these implants and do not benefit from hearing aids.

VI. Conclusion

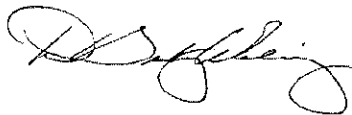
We thank you for the opportunity to provide our comments and concerns with respect to the proposed change to the scope of the hearing aid coverage exclusion and our suggested alternative to the proposal. The AAO-HNS, AOS, and ANS physician leaders and staff have met with leadership at CMS and we strongly urge HHS to ensure the proposed rule includes the necessary changes prior to final rule publication so that Medicare patients with appropriate medical indications receive needed treatment. We would welcome the opportunity to meet with you directly to answer any questions you may have regarding our comments. If you require further information, please contact Jenna Kappel, MPH, MA, Director of Health Policy at jkappel@entnet.org or 703-535-3724.

Thank you for your attention to this matter.

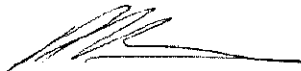
Sincerely,



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Cc: Craig Buchman, MD, AAO-HNS Chair, Implantable Hearing Devices Committee

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