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August 29, 2014

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: 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:

The American Academy of Audiology is the world's largest professional organization of, by, and for audiologists, representing over 12,000 members. The American Academy of Audiology (the "Academy") promotes quality hearing and balance care by advancing the profession of audiology through leadership, advocacy, education, public awareness, and support of research.

Below are the Academy's comments regarding the Centers for Medicare and Medicaid Services (CMS) End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Proposed Rule 1614-P, published in the Federal Register on July 11, 2014. We appreciate the opportunity to comment on proposed rule Section VII, Scope of Hearing Aid Exclusion.

Section VII: Scope of Hearing Aid Exclusion

CMS proposes to reclassify osseointegrated implants (OIs) from prosthetic devices to hearing aids. CMS states that the hearing aid exclusion encompasses all types of air conduction and bone conduction hearing aids (external, internal, or implanted), and because osseointegrated devices are bone conduction hearing aids that mechanically stimulate the cochlea, the devices do not meet the definition of a prosthetic which requires replacing "all or part of an internal body organ."¹ The Academy opposes the CMS proposal and asserts that the policy change is being proposed with no ascertainable clinical basis. As we explain in this letter, the Academy believes a sound coverage decision was made to carve out OIs in 2006. The Academy recommends that new hearing technology be considered on a case-by-case basis as to whether or not it meets the prosthetics exception criteria that CMS set forth in 2006 and that CMS develop a more detailed review process by which to evaluate new technology in the prosthetic category as is done with all other non-hearing related requests for new technology. The proposed rule's reclassification to hearing aids takes an "all or nothing" position that will significantly harm Medicare beneficiaries who have no other options available to them to facilitate hearing. Such a position is impractical for a large public health care payer, like Medicare, which must be positioned to constantly evolve with the changing demographics and health care landscape of the Medicare population. Below the Academy provides important clinical information and support for our position.

¹ 42 CFR § 414.202.

1. Hearing Loss

Hearing loss can be categorized by where or what part of the auditory system is damaged. There are three basic types of hearing loss: conductive hearing loss, sensorineural hearing loss and mixed hearing loss. Conductive hearing loss occurs when sound is not conducted efficiently through the outer ear canal to the eardrum and the tiny bones, or ossicles, of the middle ear. Conductive hearing loss usually involves a reduction in sound level, or the ability to hear faint sounds. This type of hearing loss is typically correctable by medical or surgical intervention.

Sensorineural hearing loss occurs when there is damage to the inner ear or cochlea or to the auditory pathways from the inner ear to the brain. It is permanent, and not only involves a reduction in sound level, or ability to hear sound, but also affects speech understanding, or the ability to hear clearly. Sensorineural hearing loss can be caused by diseases, birth injury, drugs that are toxic to the auditory system, and genetic syndromes. Sensorineural hearing loss may also occur as a result of noise exposure, viruses, head trauma, aging, and brain tumors. At times a conductive hearing loss occurs in combination with a sensorineural hearing loss. In other words, there may be damage in both the outer or middle ear and in the inner ear (cochlea) or auditory nerve. When this occurs, the hearing loss is referred to as a mixed hearing loss.

Unilateral hearing loss (UHL) means that hearing is normal in one ear but there is hearing loss in the other ear. The hearing loss can range from mild to profound. Approximately one out of 1000 children is born with UHL. Unilateral hearing loss can occur in both adults and children. Children with UHL are at higher risk for having academic, speech/language and social/emotional difficulties than their normal hearing peers.

The indications for use of OIs have broadened since their initial FDA approval. The devices have been successfully used and are FDA approved for unilateral or bilateral mixed or conductive hearing loss, and for unilateral sensorineural hearing loss.

2. Audiologists and Osseointegrated Implants (OIs)

Audiologists are intricately involved in the process of determining candidacy for OIs and have witnessed great improvements in hearing and quality of life for patients who obtain OIs. A clear clinical decision-making process and treatment plan exists when exploring candidacy for an OI. Audiologists engage in the following process and ongoing clinical care of the OI candidate:

- a. The patient visits a physician to discuss his or her hearing loss concerns. The physician refers the patient to an audiologist for audiological testing.
- b. If the patient comes to the audiologist first, the audiologist will conduct audiological testing and provide basic education regarding appropriate treatment options for the hearing loss that are applicable to the patient prior to referral to a physician. Following testing, the audiologist will make a referral to an otolaryngologist to initiate the OI candidacy process. Patients are frequently candidates for OIs as a result of having chronic middle ear disease, where traditional hearing aids are often medically contraindicated.
- c. Audiological testing must demonstrate the patient has a normal or near normal cochlea in at least one ear for the patient to be an OI candidate. In other words, the neural system must be intact.
- d. After the physician and audiologist determine that the patient is a candidate for an OI, surgical implantation of the OI's abutment into the mastoid process is performed by the physician (for products currently covered).

- e. The patient will have at least one, typically more than one, follow-up appointment with the audiologist for programming and fitting of the sound processor component of the implant. In addition, education is provided by the audiologist regarding optimal hearing and communication strategies and the cleaning and care of the implantation site.

3. Academy Urges Maintenance of Carve Out for Osseointegrated Implants (OIs) from Definition of Hearing Aid

On January 1, 2006, CMS modified its Medicare Benefit Policy Manual to specifically carve out OIs from the definition of hearing aids, stating:

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 prosthetic devices:

*Osseointegrated implants, i.e., devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer.*²

The Academy asserts that OIs are prosthetics and not hearing aids because they do not simply amplify sound; they replace the function of the middle ear. OIs must be implanted by specially trained physicians in circumstances where hearing aids are medically inappropriate and medically contraindicated. It is our understanding that in 2004 and 2005, Entific Medical System produced extensive evidence to CMS showing that osseointegrated devices qualified as covered prosthetics not subject to the hearing aid exclusion, and that these surgically implanted devices were reasonable and necessary and should be covered by Medicare. There are specific medical conditions where the function of the external and/or middle ear is impeded by anatomical deformities and cannot be ameliorated by amplification. Often conventional hearing aids have been unsuccessful due to poor outcomes (increased drainage, constant feedback, occlusion, inability to maintain appropriate pressure on the mastoid for appropriate conduction) or the inability of the patient to tolerate (pressure ulcers, headaches, slippage), and there is no other option than seeking to use an OI.

In 2005, CMS accepted this evidence and began to cover OIs as prosthetic devices effective January 1, 2006. According to CMS guidance, OIs 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” – in other words, they are used only for patients who have no alternative treatment and who will be left with no hearing options should CMS’s proposal be finalized.

Finally, significant hardship to Medicare beneficiaries will result from the proposed policy. The OI non-coverage decision will undoubtedly lead to a dramatic reduction in the number of people who can afford such treatment, which has been estimated at a total of \$12,000, and includes the device, surgical and audiological care, and hospital fees. As a result, many people who would otherwise remedy their hearing loss will have no affordable alternative and will continue to live with serious hearing loss issues, putting themselves and others at risk of injury. In addition to the obvious social and interpersonal difficulties that will result, studies indicate that failure to treat hearing loss is linked to increased symptoms of depression, a greater risk for falling, and an increased incidence of dementia. For those Medicare beneficiaries who previously had OIs implanted under the current Medicare policy, it was with the belief that future repairs and services would also be covered by Medicare under the prosthetics benefit. Yet, under the CMS proposal, Medicare beneficiaries

² CMS Chapter 15, section 100, Medicare Benefit Policy Manual, 100 - Hearing Aids and Auditory Implants (Rev. 39; Issued: 11-10-05; Effective: 11-10-05; Implementation: 12-12-05) (emphasis added).

who currently use OIs may not be able to afford needed repairs and will no longer utilize the device, rendering it useless and wasteful to the Medicare program.

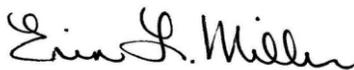
The Academy urges CMS to continue to provide coverage for OIs under the prosthetics classification. In addition, the Academy proposes the following criteria be considered when evaluating hearing technology under the prosthetics category:

- Patients with conductive hearing loss, mixed hearing loss and unilateral (single-sided) sensorineural (permanent) hearing loss should have a covered benefit for treatment with a prosthetic;
- Devices with the following characteristics should also be considered hearing prosthetics:
 - a) Replace all or part of the function of the ear;
 - b) Restore hearing without amplifying sound waves, and
 - c) Provide acoustic energy to one or both cochleas by transmission of the energy through bone.
- Proper use of prosthetics follows the Medicare medical model, which requires a physician referral to complete a diagnosis and treatment plan, and only for conditions where a hearing aid is medically contraindicated (e.g., due to congenital malformations, chronic disease such as chronic ear drainage, and/or severe to profound sensorineural hearing loss.).

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The Academy appreciates the opportunity to comment on this proposed rule. Please contact Ed Sullivan, Interim Executive Director, at 800-222-2336 ext. 1034 or via email at esullivan@audiology.org should you have any questions regarding the Academy's comment letter.

Sincerely,



Erin L. Miller, AuD
President, American Academy of Audiology