



AMERICAN COCHLEAR IMPLANT ALLIANCE

Research. Advocacy. Awareness.

August 15, 2014
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1614-P
PO Box 8013
Baltimore, MD 21244-1850

Dear CMS Administrator Tavenner:

We are writing regarding the proposal by the Centers for Medicare and Medicaid Services to modify the existing regulation §411.15(d)(1) to specify that the hearing aid exclusion encompasses Osseointegrated Implants. CMS states that these prosthetic devices function like hearing aids. We disagree that the surgically implanted Auditory Osseointegrated Implant, which replaces non-functioning or absent body parts, is a hearing aid and our comments present an argument for continued coverage.

The American Cochlear Implant Alliance (ACI Alliance) is a non-profit, 501(c)3 whose mission is to advance the gift of hearing provided by cochlear implantation and other implantable prosthetic hearing implants through research, advocacy and awareness. The membership includes clinicians who provide the intervention (e.g., ENT surgeons, audiologists, speech language pathologists), other professionals on implant teams including social workers and psychologists, teachers of deaf children, researchers, parents of children with cochlear implants, adult cochlear implant recipients, and other advocates. The organization seeks to ensure appropriate access to, and quality of, clinical care relating to cochlear implantation, auditory brainstem implants, and Osseointegrated Implants. An annual research-based scientific meeting is convened. The majority of ACI Alliance clinicians serve Medicare patients and approximately 50% provide the Auditory Osseointegrated Implant to appropriate patients at their clinics.

American Cochlear Implant Alliance opposes the change in definition that will result in a lack of Medicare coverage for hearing prosthetic devices. We respectfully present the following six points on Auditory Osseointegrated Implants to clarify why this intervention should continue to be a covered service under Medicare. As other prostheses are developed and seek Medicare coverage, they can be evaluated in like fashion.

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1. How osseointegrated implants differ from hearing aids
2. Candidate population and benefits derived from the Osseointegrated Implant
3. How candidacy is determined
4. Summary of peer reviewed literature over 30 years of clinical use
5. Demonstrated cost effectiveness
6. Broad benefits of sensitive hearing

1. **Auditory Osseointegrated Implants are inherently different in function from hearing aids.** Air conduction hearing aids operate by amplifying sound to overcome damaged hair cells in the cochlea or inner ear. Bone conduction hearing aids utilize a tight band placed around the user's head to transmit vibrations of sound to the bones in the head. This band is uncomfortable and generally intolerable for the wearer after several hours of use. There are four key differences between both types of hearing aids and the Auditory Osseointegrated Implant, as summarized in the table below:

Distinctions between an Osseointegrated Implant and a Hearing Aid

Question	Osseointegrated Implant	Hearing Aid
Is surgery involved?	Yes	No
Is the device implanted?	Yes	No
Does the bone surrounding the implant site grow into the device, rendering the device a permanent fixture?	Yes	No
Does the implant replace the function of an absent or diseased body part?	Yes, it replaces two essential functions: the collection and transfer of sound vibrations normally enabled by the external ear canal, eardrum, and ossicles of the middle ear	No

The proposed rule at page 40295 references the Medicare definition of a prosthetic:

Prosthetic devices are a Medicare benefit category defined at section 1861(s)(8) of the Act which, in part, states "prosthetic devices (other than dental) which replace all or part of an internal body organ."

The language of the proposed rule, also on page 40295 of the Federal Register states that:

...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).

The Osseointegrated Implant is both a prosthetic and an intervention that replaces the function of an internal body organ. Individuals who are candidates for Osseointegrated Implants have hearing abnormalities such that they require replacement of a body organ and cannot be or have not been

helped by a hearing aid. The language of the proposed rule published on July 11, 2014 would appear to support coverage of the Osseointegrated Implant stating:

*...we consider that a hearing aid provides assistance or “aid” to hearing that already exists via a **functioning** ear.* [emphasis added]

Since candidates for Osseointegrated Implants do not have a functioning ear(s) and cannot benefit even from the most advanced hearing aids, such individuals fit the Medicare definition for prosthetics.

- 2. Candidate population and benefits derived from the Osseointegrated Implant.** Candidates for Osseointegrated Implants have complex and/or severe malformations of the middle and/or outer ear including congenital anomalies of the skull or acquired infections and tumors that do not allow use of hearing aids. Osseointegrated devices provide the only access to hearing for such patients.

The Osseointegrated Implant replaces the ear canal and middle ear to enable sound transmission to the inner ear. In the case of single-sided deafness in which there is a non-functional cochlea, the transmission of sound across the skull enables hearing sounds from the deaf side, without requiring that technology be placed in the only hearing ear—a critical feature of the Osseointegrated Implant that improves speech understanding. In such instances, Osseointegrated Implants effectively replace the non-functioning cochlea on the deaf side.

- 3. How is candidacy determined?** Prior to consideration for an Osseointegrated Implant, patients are thoroughly evaluated for benefit with a hearing aid(s). Although the candidacy pool is diverse in terms of the characteristics of their hearing system deficiencies, there is a common thread in that all candidates for an Osseointegrated Implant are absent one or more working body organs. Only those patients whose ear disease is so severe that they do not have a functioning body part and require replacement of a portion of the ear such that a hearing aid cannot provide benefit is considered for an Osseointegrated Implant. These indications are consistent with CMS coverage policy as noted on page 40295 of the Federal Register:

...we consider that a hearing aid provides assistance or “aid” to hearing that already exists via a functioning ear.

- 4. Summary of peer reviewed literature.** We conducted a review of papers published on Osseointegrated Implants in peer-reviewed journals over the past twenty years for our response to this proposed rule-making. In fact, the devices have an even longer history of use spanning three decades. Osseointegrated Implants are used and have been clinically evaluated around the world; the papers reviewed were authored by scientists and clinicians from the United States, Australia, Canada, Sweden, the United Kingdom, the Netherlands, Belgium, Germany, Spain, France, and Poland. Osseointegrated Implants are considered a prosthetic for appropriately evaluated patients of all ages in these and other developed countries of the world. The large body of literature on this intervention demonstrates diversity of the patient population but also an important commonality—there are no other efficacious options for patients to hear. The Bibliography is attached. Findings across the eighty-seven papers that we reviewed are summarized below:

Audiology

- Objective audiometric measures and subjective patient satisfaction surveys demonstrate significant improvement in unaided and aided sound field thresholds as well as speech discrimination in quiet and in noise for former users of conventional bone conduction hearing aids as the device replaces the severely damaged parts of the ear system. Patients report improved quality of life with enhanced speech intelligibility, better sound comfort, elimination of discomfort and irritation on the head (from conductive hearing aids), and increased confidence in carrying out conversations and daily living.
- Reduced frequency of ear infection and discharge, particularly among patients with suppurative otitis media (Watson 2008, Badran 2006).
- In a 12-center study of patients with chronic otitis media or draining ears (18) and external auditory canal stenosis or aural atresia (7), each patient had an average improvement of 32+/-19 dB post surgery (Lustig 2001).
- With sound processor technology advances, outcomes for patients with conductive and mixed hearing loss improved over time (Pfiffner 2011).

Outcomes

Mixed Conductive Hearing Loss

- Patients with mixed hearing loss present special challenge as amplification drives powerful digital hearing aids to their limit and introduces distortion through saturation. Bypassing the conductive component of the damaged hearing system with an Osseointegrated Implant focuses on compensating for the sensorineural component of the hearing loss and allows improvements across audibility, speech understanding and sound quality. (Flynn 2009, Verhaegen 2009, Orus 2011).
- One study measured average gain in conversational frequencies (0.5 to 4kHz) ranging from 43 to 51 dB (Orus 2011).

Conductive Hearing Loss

- Patients with bilateral congenital atresia (many had Treacher Collins syndrome) fit bilaterally with Osseointegrated Implants showed significant improvement in speech perception in quiet and noise as well as sound localization (van der Pouw 1998).
- Patients with a range of ear abnormalities (discharging mastoid cavities, chronic active otitis media, congenital ear problems, otosclerosis, acoustic neuroma and other unilateral hearing loss) benefit from Osseointegrated Implants. The congenital atresia group scored highest with +45 (95% CI) though Osseointegrated Implants. Following acoustic neuroma surgery, there was also benefit with a score of +22.2 (McLarnon 2004).
- Osseointegrated Implants were beneficial in optimizing binaural hearing in patients with severe (40-60 dB) unilateral conductive hearing loss (Hol 2005).

Single Sided Deafness

- Osseointegrated Implants in Single Sided Deafness were correlated with high patient satisfaction and measurable improvements in speech perception in noise. The implant does not reliably improve sound localization (Saroul 2013, Wazen 2010, Zeitler 2012).

- The Glasgow Benefit Inventory revealed that 91 percent of patients reported improvement in their quality of life (Wazen 2010).

Cost Effectiveness / Quality of Life

- Savings in health care dollars for patients with chronic suppurative otitis media exacerbated by plugging the ear with a hearing aid. After osseointegrated surgery, there was a substantial reduction in the number of medical visits and medications provided to address repeated ear infections with overall cost savings (Watson 2008, Badran 2006).
- Glasgow Benefit Inventory was used to assess changes in patients' quality of life. Average benefit score was 38, a significant change (Soanez-Camoon 2007, Wazen 2010).

- 5. Demonstrated cost effectiveness.** The Osseointegrated Implant has a record of demonstrated cost effectiveness in studies conducted around the world including the UK and Canada, both of which require that cost effectiveness be demonstrated as part of the coverage decision-making for national healthcare. In a Medical Policy developed by UCare (Canada) effective January 1, 2014, it is noted that the clinical evidence supports use of Osseointegrated Implants based on data for patients with conductive or mixed hearing loss who meet medical and audiologic criteria as well as patients with single-sided sensorineural deafness.

Cost effectiveness has been demonstrated across the patient population for those who are appropriate candidates but for patients with chronic suppurative otitis media exacerbated by plugging the ear with a hearing aid, the cost savings is particularly important. After osseointegrated surgery, there is a significant reduction in the number of medical visits and prescribed medications to address repeated infections from ongoing ear disease for patients who previously used hearing aids.

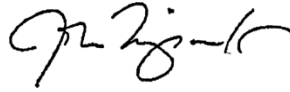
- 6. Broad benefits of sensitive hearing.** The above discussion focuses on benefit to the candidate population based upon improved hearing via the Osseointegrated Implant. Recent studies have demonstrated a link between hearing loss and other health conditions in the older Medicare population. While hearing loss is viewed by most as a communication disorder, it has more wide-ranging consequences as it increases the risk of falls and injuries, it tends to reduce an individual's activity and participation, and it has shown to decrease the quality of life. With regard to falls, in a study of 423 women (mean age of 68 years), there was a significant increase in the number of falls—even controlling for postural balance. The most significant findings associated with hearing loss relate to the personal consequences as individuals report that hearing loss was their own most significant health concern as individuals indicate that they are fearful that they will miss an important event that could result in a threat to their safety. Older people have greater difficulty in understanding speech in noise (Pichora-Fuller et al, 1995). A series of recent studies have found an association between hearing loss and cognitive decline including dementia (Lin et al., 2013; Gallacher et al., 2012; Lin et al., 2011) even when the test mechanism does not rely upon hearing. Because these findings are relatively recent and not fully understood, scientists do not yet understand the process of cognitive decline associated with hearing loss. However, it does provide additional justification for providing Osseointegrated Implants to this population of Medicare beneficiaries who have no other options for hearing.

We appreciate the opportunity to comment on this proposed rule. Please do not hesitate to contact us if you have questions on these comments or wish to discuss other elements, which we may not have addressed here.

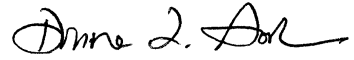
Sincerely,



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