AMERICAN COCHLEAR IMPLANT ALLIANCE

Research. Advocacy. Awareness.

Facts on Auditory Implanted Devices

1. **Osseointegrated devices require the surgical insertion of an implant into the mastoid bone and are prosthetic devices—not hearing aids**. The Auditory Osseointegrated Device was defined as a prosthetic CMS in 2006 and the device still fits the description today. CMS should apply the same prosthetic standard to this and other auditory devices just as it was developed, written and applied for the original 2006 CMS coverage policy. Other auditory devices requiring surgery may also be classified as auditory prosthetic devices if they fit the definition.

2. **Patients who use Auditory Osseointegrated Devices do not benefit from hearing aids**. In fact, many candidates have congenital anomalies of the skull or acquired infections and tumors that DO NOT ALLOW THEIR USE OF HEARING AIDS. Osseointegrated device technology provides their only access to effective hearing. This technology replaces their ear canal and middle ear to enable sound transmission to the inner ear. In the case of single-sided deafness, 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 osseointegrated technology that improves speech understanding. In this case, osseointegrated implants effectively replace the non-functioning cochlea on the deaf side. Other devices for people with other indications may also be determined to be prosthetics and outside of the hearing aid definition.

3. **Osseointegrated devices have been in use for over 30 years** and have been shown to provide important hearing outcomes and to be cost effective. There is a large body of published literature to support use for appropriate indications. Appropriate indications include conductive or mixed hearing loss and an inability to wear or benefit from a hearing aid because of no ear canal, tympanic membrane, or ossicular problems; a mastoid cavity with active disease; severe feedback (when using a hearing aid) related to a large meatus; or sensorineural deafness in one ear with normal or near normal hearing in the contralateral ear.

4. **Clinicians recommend use of prosthetic surgical hearing devices only after a thorough evaluation.** Patients should always be evaluated for hearing aids first. For most patients with conductive or mixed hearing loss and/or ear malformations like atresia or microtia or single sided deafness, there is no other option to hear.

5. **Cost effectiveness has been demonstrated across the patient population** 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 reduction in the number of medical visits and medications to address repeated infections for such patients who previously used hearing aids.

6. **Hearing loss is associated with greater incidence, and also increased levels of, dementia in older adults**. The cost of treating individuals with dementia is substantially greater than providing access to hearing and the interconnected ability to carry out activities of daily living. Medicare's mission in treating its beneficiaries should take into effect the potential impact of hearing loss on the general health of individuals.