

The "HEARING BONE'S" Connected to the WHAT?

Hearing loss may signal other important health issues



**CARDIOVASCULAR
DISEASE (CVD)**
Could the ear be a
window to the heart?
Hearing loss and
CVD linked



**ALZHEIMER'S
& DEMENTIA**
Dementia risk
may be up to
5X higher with
hearing loss



DIABETES
Hearing loss 2X
as likely for those
with diabetes



DEPRESSION
Symptoms go down,
quality of life goes up
with hearing aid use



**HEARING LOSS
IS CONNECTED TO
OTHER HEALTH
CONDITIONS**



HOSPITALIZATION
32% more likely for
older adults with
hearing loss



FALLING
Hearing loss
tied to 3-fold
risk of falling



**CHRONIC
KIDNEY
DISEASE (CKD)**
Moderate CKD
associated with
43% increased risk
of hearing loss



MORTALITY
Hearing loss tied to
greater risk of dying
for older men

DURABLE MEDICAL EQUIPMENT, PROSTHETICS,
ORTHOTICS AND SUPPLIES PROPOSED RULE

CONTINUED COVERAGE OF
OSSEOINTEGRATED IMPLANTS FOR
MEDICARE BENEFICIARIES

October 6, 2014

SUMMARY

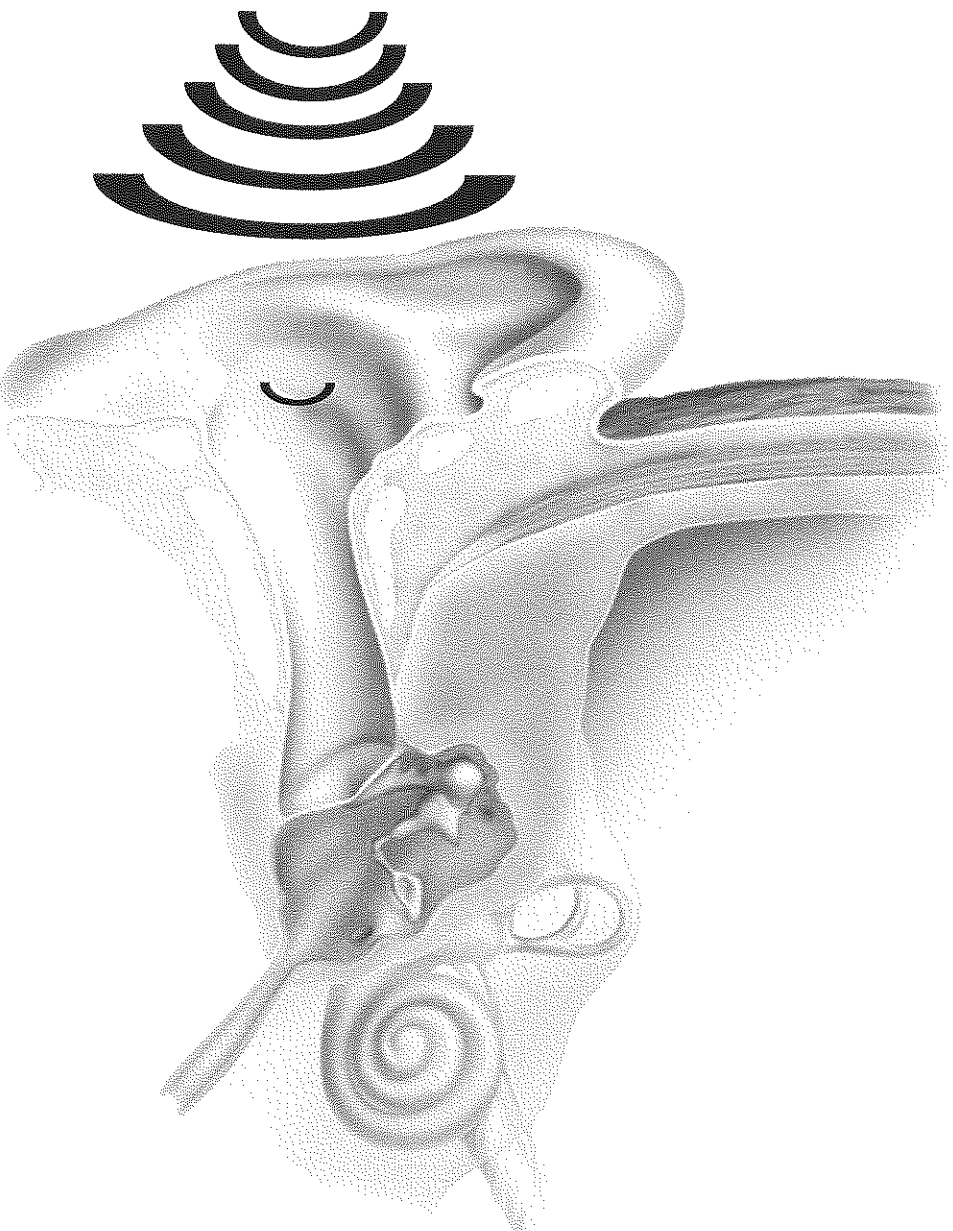
Proposed Rule: On July 2, 2014, CMS issued a Proposed Rule that would reclassify osseointegrated devices as hearing aids, rendering them non-covered under the hearing aid exclusion.

These Are Covered Prosthetic Devices: CMS drew the correct conclusion in 2006 in deciding to cover osseointegrated devices as prosthetics that replace the function of the middle ear (or in certain cases, the non-functioning cochlea).

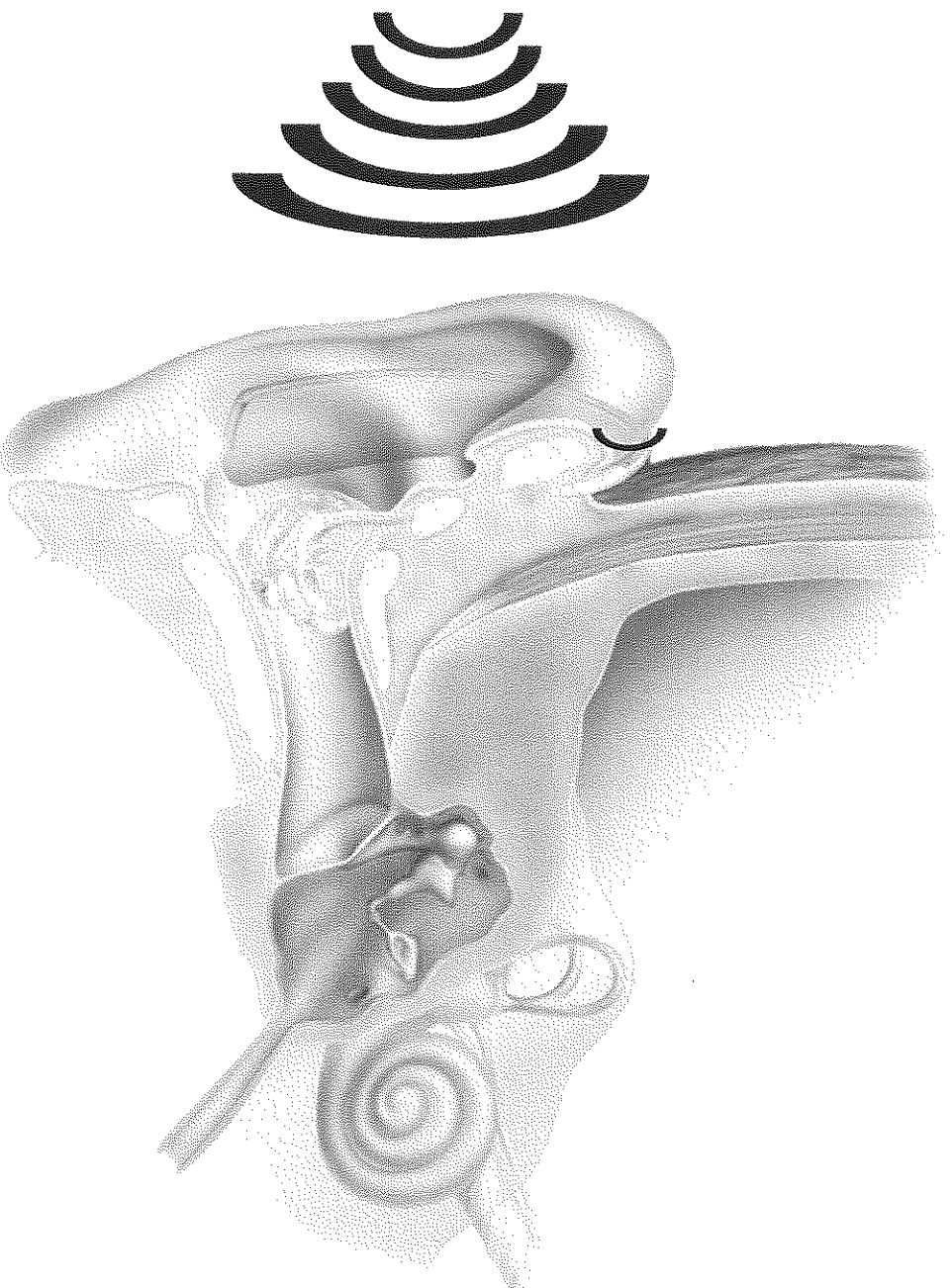
These Patients Have No Other Option: These osseointegrated devices provide a hearing solution to patients who have no other viable treatment option for their hearing loss. Hearing aids do not and cannot provide clinical benefit.

Clinical and Bipartisan Congressional Support: 300+ published articles supporting clinical effectiveness of osseointegrated implants; multiple hearing industry professional organizations submitted comments to CMS in favor of continued coverage of osseointegrated devices; Bipartisan support for continued coverage of osseointegrated devices from House Hearing Health Caucus

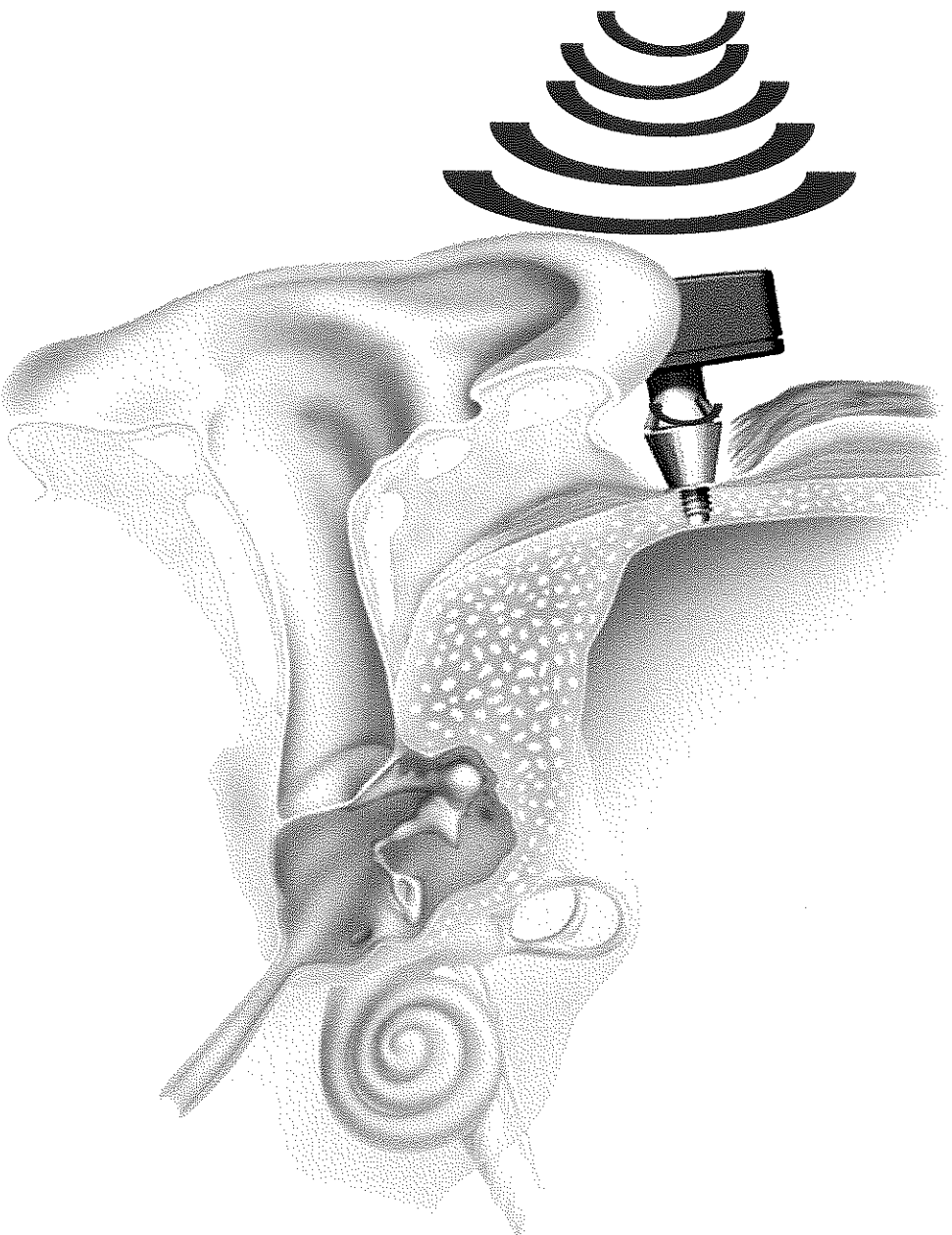
HOW WE HEAR



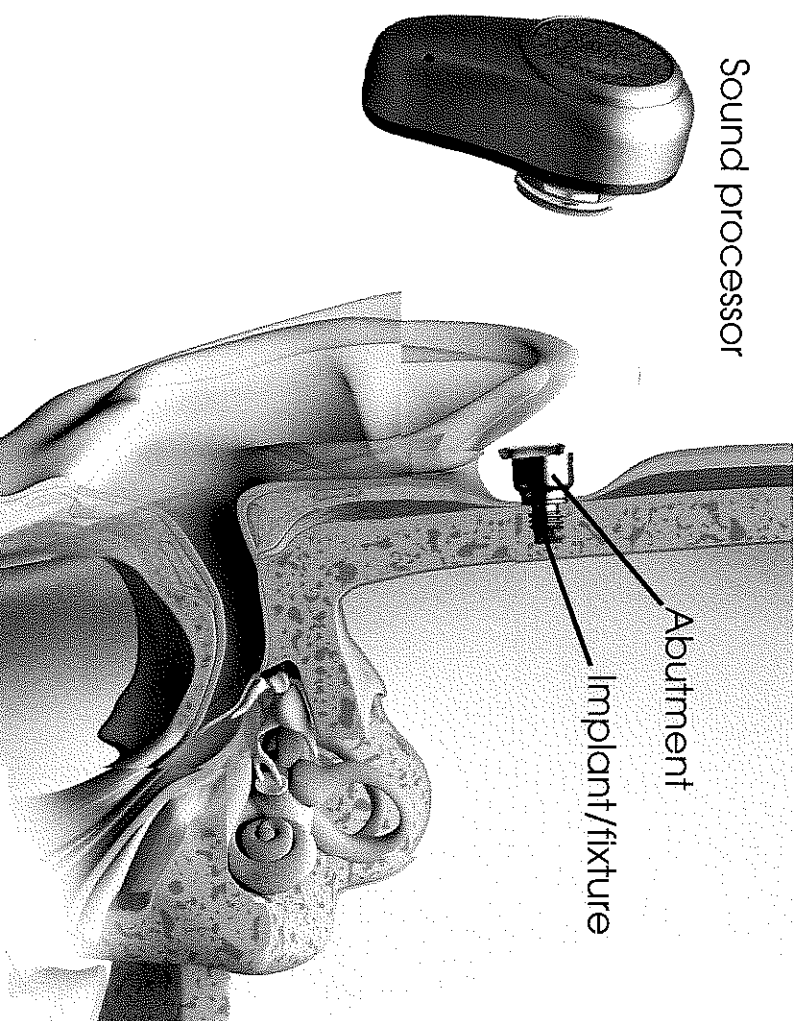
BEHIND-THE-EAR HEARING AID



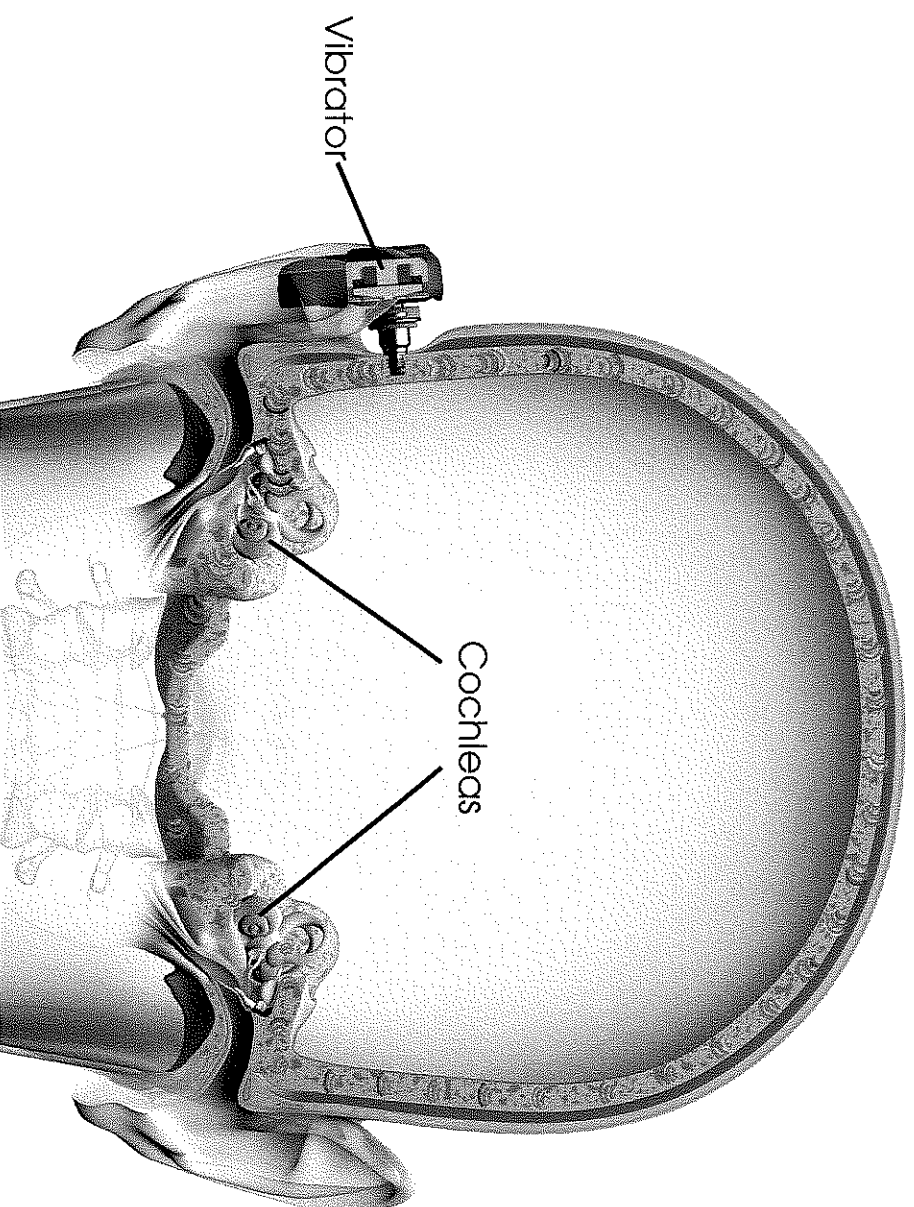
HEARING WITH OSSEOINTEGRATED IMPLANTS



OSSEOINTEGRATED IMPLANT SYSTEM



VIBRATION TRANSMITS TO BOTH SIDES



OSSEOINTEGRATED IMPLANT BONE CONDUCTION

Works independently of ear canal and middle ear

Direct transmission gives clear and natural sound

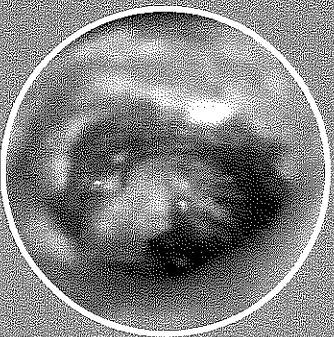
Preoperative testing possible

High wearing comfort

Safe and straightforward surgery

Predictable outcome

FOR SOME PATIENTS, TRADITIONAL HEARING AIDS ARE CONTRAINDICATED



Conductive/mixed hearing loss
due to chronic infection;
worsened by occluding the
ear canal with hearing aid



Conductive/mixed hearing loss
due to microtia/atresia and other
congenital defects

No Clinical Benefit

CANDIDATES WITH CONGENITAL DEFECTS HEARING AIDS ARE CONTRAINDICATED

Congenital microtia/atresia

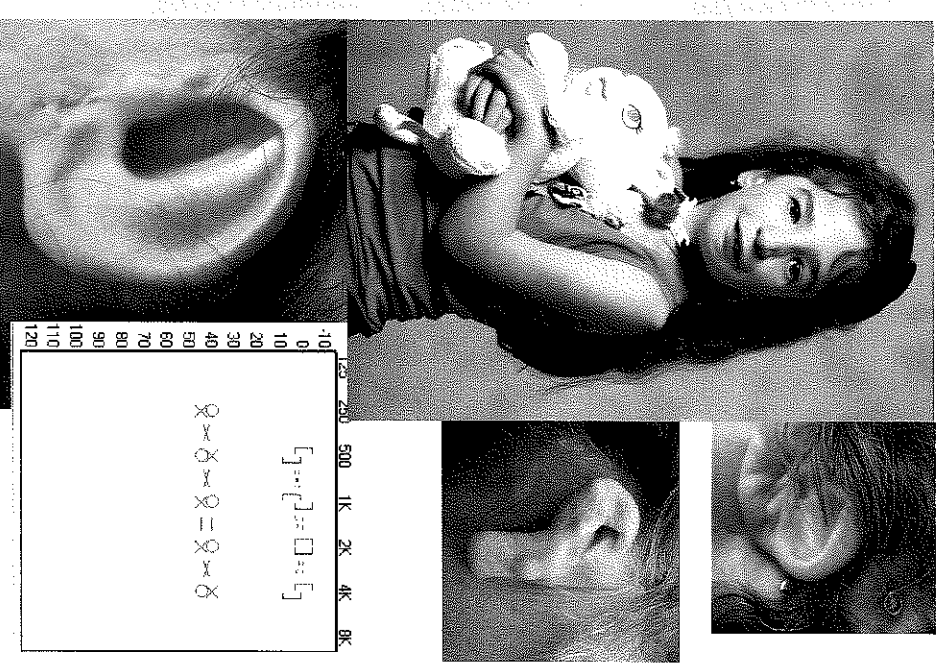
- Born with malformation or no outer ear

Syndromes

- Treacher Collins, Goldenhar

Most often conductive hearing loss

- Normal inner ear



CURRENT CMS POSITION (SINCE 2006)

In 2005, CMS reclassified the Baha Implant System as an Osseointegrated Implant (prosthetic implant) eff. Jan. 1, 2006, finding it met Medicare's definition of a prosthetic for coverage and payment:

CMS 100 - Hearing Aids and Auditory Implants (Rev. 39; Issued: 11-10-05; Effective: 11-10-05; Implementation: 12-12-05)

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.

CMS PROPOSED RULE (JULY 2ND, 2014)

On July 2, 2014, CMS issued a Proposed Rule that would treat osseointegrated implants like the Baha Implant System as a hearing aid. Under the Proposed Rule:

CMS re-examined the scope of the statutory hearing aid exclusion in light of multiple benefit category determination requests in recent years.

CMS now purports to “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.”

Without explanation for reversing its position, CMS now opines that these devices “do not replace the function of an internal body organ and thus are not considered prosthetic devices under Medicare payment policy.”

OSSEOINTEGRATED DEVICES SHOULD REMAIN COVERED AS PROSTHETICS

- Covered prosthetic devices are “**prosthetic devices (other than dental) which replace all or part of an internal body organ** (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.”
- Consistent with the Social Security Act’s definition, osseointegrated implants are prosthetics and replace the function of the ear canal, ossicular chain and the cochlea.

42 U.S.C. § 1861(s)(8) (Emphasis added)

CONCLUSION

- *Osseointegrated implants are the modality of last resort for many patients and replace the function of the middle ear (or in certain patients, the non-functioning cochlea).*
- *Candidates for osseointegrated implants do not get benefit from hearing aids.*
- *Patients with conditions such as aural atresia and microtia will be left without an effective option as they are not candidates for traditional hearing aids.*
- *Effectiveness well documented in 300+ clinical publications*
- *Professional support for continued coverage of osseointegrated devices from leading industry associations (including AAO, ACIA, AAA)*
- *More than 40,000 US Recipients since FDA approval in 1995*
- *More than 6,500 recipients 65+*

QUESTIONS?