INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Note: This policy does not address assistive listening devices, computers, transmitters or similar products.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

The following hearing aids may not be covered for certain benefit plans. Refer to the member specific benefit plan document to determine if coverage applies.

Wearable Hearing Aids (Including Non-Implantable Bone Conduction Hearing Aids Utilizing a Headband)

- Refer to the member specific benefit plan document to determine if coverage applies.
- Standard plans include coverage for wearable hearing aids that are purchased as a result of a written recommendation by a Physician. Benefits are provided for the hearing aid and for charges for the associated fitting and testing.
- The Wearable Hearing Aids benefit does not include batteries, accessories, or dispensing fees.

Semi-Implantable Electromagnetic Hearing Aids (SEHA)

- Refer to the member specific benefit plan document to determine if coverage applies.
- Standard plans include coverage for a SEHA that meets the proven criteria below.
- Standard plans do not have dollar limits or repair/replacement limits on SEHA.
• The SEHA benefit does not include batteries, accessories, or dispensing fees.

**Bone Anchored Hearing Aids**
• Refer to the member specific benefit plan document to determine if coverage applies.

**Totally Implanted Hearing Systems**
• Totally implanted hearing systems are excluded from coverage in plans that exclude unproven and/or non-medically necessary services.

**Partially Implantable Bone Conduction Hearing Aid with Magnetic Coupling**
• Partially implantable bone conduction hearing aids with magnetic coupling are excluded from coverage in plans that exclude unproven and/or non-medically necessary services.

**Intraoral Bone Conduction Hearing Aids**
• Intraoral bone conduction hearing aids are excluded from coverage in plans that exclude unproven and/or non-medically necessary services.

**Laser or Light Based Hearing Aids**
• Laser or light based hearing aids are excluded from coverage in plans that exclude unproven and/or non-medically necessary services.

Frequency modulated (FM) systems can be used as an extension or accessory of hearing aids. FM systems do not meet the definition of Covered Health Service and are excluded from coverage. These do not prevent, diagnose or treat a sickness or injury, and are not integral to the hearing aid itself.

**Essential Health Benefits for Individual and Small Group**
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

**COVERAGE RATIONALE**

**Wearable Hearing Aids (Including Non-Implantable Bone Conduction Hearing Aids Utilizing a Headband)**
Hearing aids required for the correction of a hearing impairment (a reduction in the ability to perceive sound which may range from slight to complete deafness) are proven and medically necessary.

Bilateral or unilateral bone-anchored hearing aids utilizing a headband (without osseointegration) are proven and medically necessary for hearing loss in a patient who is not a candidate for an air-conduction hearing aid and when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions. See the FDA section for more information.

**Semi-Implantable Electromagnetic Hearing Aids (SEHA)**
A semi-implantable electromagnetic hearing aid is proven and medically necessary for sensorineural hearing loss in a patient who is not a candidate for an air-conduction hearing aid and when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions. See the FDA section for more information.

**Bone Anchored Hearing Aids**

**Implantable Bone-Anchored Hearing Aid (BAHA) for Sensorineural Hearing Loss**
A unilateral implantable bone-anchored hearing aid is proven and medically necessary for sensorineural hearing loss in one ear in a patient who is not a candidate for an air-conduction hearing aid and when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions. See the FDA section for more information.
Unilateral or bilateral implantable bone-anchored hearing aids are proven and medically necessary for sensorineural hearing loss in both ears when both of the following criteria are present:
- The poorer ear is not a candidate for an air-conduction hearing aid due to a speech reception threshold of 70 dB or more OR a word discrimination score of less than 60%; and
- The better hearing ear has a speech reception threshold of 35 dB or less and a speech discrimination score of 60% or more.

**Implantable Bone-Anchored Hearing Aid (BAHA) for Conductive or Mixed Hearing Loss**
A unilateral implantable bone-anchored hearing aid is proven and medically necessary for conductive or mixed hearing loss in one or both ears in a patient who is not a candidate for an air-conduction hearing aid and when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions.
See the [FDA](#) section for more information.

Bilateral implantable bone-anchored hearing aids are proven and medically necessary for conductive or mixed hearing loss in both ears in a patient who is not a candidate for an air-conduction hearing aid and when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions.
See the [FDA](#) section for more information.

**Totally Implanted Hearing Systems**
Totally implanted hearing systems are unproven and not medically necessary for hearing loss.
There is inadequate evidence demonstrating the efficacy of totally implanted hearing systems for treating hearing loss or deafness. Well-designed studies with larger patient populations and longer follow-up are required to demonstrate the safety and benefits of these devices.

**Partially Implantable Bone Conduction Hearing Aid with Magnetic Coupling**
Partially implantable magnetic bone conduction hearing devices are unproven and not medically necessary for hearing loss.
There is limited evidence to support the use of partially implantable magnetic bone conduction hearing devices to treat hearing loss. The evidence assessing the effectiveness of this device is limited to preliminary uncontrolled studies with small populations. Additional studies with larger populations and long-term follow-up are needed to evaluate improvement of hearing with this device.
See the [Description of Services](#) section for more information.

**Intraoral Bone Conduction Hearing Aids**
An intraoral bone conduction hearing aid is unproven and not medically necessary for treating hearing loss.
There is insufficient evidence to support the use of an intraoral bone conduction hearing aid to treat hearing loss. The quality of the studies was low due to small study populations, short follow-up, and lack of randomization and appropriate control groups. Future studies with larger populations of patients wearing the device for longer periods are needed to evaluate hearing benefits and device safety.

**Laser or Light Based Hearing Aids**
Laser or light based hearing aids (e.g., Earlens Contact Hearing Device) are unproven and not medically necessary for treating hearing loss.
The evidence assessing the effectiveness of this device is limited. Additional studies with larger populations and long-term follow-up are needed to evaluate improvement of hearing with hearing aids that use light to transmit sound.

**DEFINITIONS**

**Conductive Hearing Loss:** Occurs when sound is not conducted efficiently through the outer ear canal to the eardrum and the tiny bones (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 can often be corrected medically or surgically.

**Degree of Hearing Loss:**

<table>
<thead>
<tr>
<th>Degree of Hearing Loss</th>
<th>Range (dbHL = decibels hearing level)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Hearing</td>
<td>10 to 15 dBHL</td>
</tr>
<tr>
<td>Slight Loss</td>
<td>16 to 25 dBHL</td>
</tr>
</tbody>
</table>
**Frequency Modulation Systems (Auditory Trainers):** A wireless connection to the listener’s amplification system.

**Hearing Aids:** Hearing aids are sound-amplifying devices designed to aid people who have a hearing impairment. Most hearing aids share several similar electronic components, and technology used for amplification may be analog or digital. (Semi-implantable electromagnetic hearing aids and bone-anchored hearing aids are classified by the U.S. Food and Drug Administration (FDA) as hearing aids. Some non-wearable hearing devices are described as hearing devices or hearing systems. Because their function is to bring sound more effectively into the ear of a person with hearing loss, for the purposes of this policy, they are hearing aids).

**Mixed Hearing Loss:** Occurs when a conductive hearing loss occurs in combination with a sensorineural hearing loss (SNHL). In other words, there may be damage in the outer or middle ear and in the inner ear (cochlea) or auditory nerve.

**Sensorineural Hearing Loss (SNHL):** Occurs when there is damage to the inner ear (cochlea), or to the nerve pathways from the inner ear to the brain. Most of the time, SNHL cannot be medically or surgically corrected. This is the most common type of permanent hearing loss.

### APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>92590</td>
<td>Hearing aid examination and selection; monaural</td>
</tr>
<tr>
<td>92591</td>
<td>Hearing aid examination and selection; binaural</td>
</tr>
<tr>
<td>92592</td>
<td>Hearing aid check, monaural</td>
</tr>
<tr>
<td>92593</td>
<td>Hearing aid check, binaural</td>
</tr>
<tr>
<td>92594</td>
<td>Electroacoustic evaluation for hearing aid; monaural</td>
</tr>
<tr>
<td>92595</td>
<td>Electroacoustic evaluation for hearing aid; binaural</td>
</tr>
<tr>
<td>69799</td>
<td>Unlisted procedure, middle ear</td>
</tr>
</tbody>
</table>

**Semi-Implantable Electromagnetic Hearing Aids (SEHA)**

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>69710</td>
<td>Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone</td>
</tr>
<tr>
<td>69711</td>
<td>Removal or repair of electromagnetic bone conduction hearing device in temporal bone</td>
</tr>
<tr>
<td>69714</td>
<td>Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy</td>
</tr>
<tr>
<td>69715</td>
<td>Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy</td>
</tr>
<tr>
<td>69717</td>
<td>Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Degree of Hearing Loss</th>
<th>Range (dbHL = decibels hearing level)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild Loss</td>
<td>26 to 40 dBHL</td>
</tr>
<tr>
<td>Moderate Loss</td>
<td>41 to 55 dBHL</td>
</tr>
<tr>
<td>Moderately Severe Loss</td>
<td>56 to 70 dBHL</td>
</tr>
<tr>
<td>Severe Loss</td>
<td>71 to 90 dBHL</td>
</tr>
<tr>
<td>Profound Loss</td>
<td>91 dBHL or more</td>
</tr>
</tbody>
</table>

(ASHA, Type, Degree and Configuration of Hearing Loss; Clark, 1981)
<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>69718</td>
<td>Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy</td>
</tr>
</tbody>
</table>

*CPT® is a registered trademark of the American Medical Association*

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S0618</td>
<td>Audiometry for hearing aid evaluation to determine the level and degree of hearing loss</td>
</tr>
<tr>
<td>V5010</td>
<td>Assessment for hearing aid</td>
</tr>
<tr>
<td>V5011</td>
<td>Fitting/orientation/checking of hearing aid</td>
</tr>
<tr>
<td>V5014</td>
<td>Repair/modification of a hearing aid</td>
</tr>
<tr>
<td>V5020</td>
<td>Conformity Evaluation</td>
</tr>
<tr>
<td>V5264</td>
<td>Ear mold/insert, not disposable, any type</td>
</tr>
<tr>
<td>V5265</td>
<td>Ear mold/insert, disposable, any type</td>
</tr>
<tr>
<td>V5275</td>
<td>Ear impression, each</td>
</tr>
</tbody>
</table>

**Fitting and Testing of Hearing Aids**

**Semi-Implantable Electromagnetic Hearing Aids (SEHA)**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2230</td>
<td>Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear</td>
</tr>
<tr>
<td>V5095</td>
<td>Semi-implantable middle ear hearing prosthesis</td>
</tr>
</tbody>
</table>

**Bone Anchored Hearing Aids (BAHA)**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8690</td>
<td>Auditory osseointegrated device, includes all internal and external components</td>
</tr>
<tr>
<td>L8691</td>
<td>Auditory osseointegrated device, external sound processor, replacement</td>
</tr>
<tr>
<td>L8692</td>
<td>Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment</td>
</tr>
<tr>
<td>L8693</td>
<td>Auditory osseointegrated device abutment, any length, replacement only</td>
</tr>
</tbody>
</table>

**Wearable Hearing Aids**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>V5030</td>
<td>Hearing aid, monaural, body worn, air conduction</td>
</tr>
<tr>
<td>V5040</td>
<td>Hearing aid, monaural, body worn, bone conduction</td>
</tr>
<tr>
<td>V5050</td>
<td>Hearing aid, monaural, in the ear</td>
</tr>
<tr>
<td>V5060</td>
<td>Hearing aid, monaural, behind the ear</td>
</tr>
<tr>
<td>V5070</td>
<td>Glasses, air conduction</td>
</tr>
<tr>
<td>V5080</td>
<td>Glasses, bone conduction</td>
</tr>
<tr>
<td>V5100</td>
<td>Hearing aid, bilateral, body worn</td>
</tr>
<tr>
<td>V5120</td>
<td>Binaural, body</td>
</tr>
<tr>
<td>V5130</td>
<td>Binaural, in the ear</td>
</tr>
<tr>
<td>V5140</td>
<td>Binaural, behind the ear</td>
</tr>
<tr>
<td>V5150</td>
<td>Binaural, glasses</td>
</tr>
<tr>
<td>V5170</td>
<td>Hearing aid, CROS, in the ear</td>
</tr>
<tr>
<td>V5180</td>
<td>Hearing aid, CROS, behind the ear</td>
</tr>
<tr>
<td>V5190</td>
<td>Hearing aid, CROS, glasses</td>
</tr>
<tr>
<td>V5210</td>
<td>Hearing aid, BICROS, in the ear</td>
</tr>
<tr>
<td>V5220</td>
<td>Hearing aid, BICROS, behind the ear</td>
</tr>
<tr>
<td>V5230</td>
<td>Hearing aid, BICROS, glasses</td>
</tr>
<tr>
<td>V5242</td>
<td>Hearing aid, analog, monaural, CIC (completely in the ear canal)</td>
</tr>
<tr>
<td>V5243</td>
<td>Hearing aid, analog, monaural, ITC (in the canal)</td>
</tr>
<tr>
<td>V5244</td>
<td>Hearing aid, digitally programmable analog, monaural, CIC</td>
</tr>
</tbody>
</table>
### HCPCS Code | Description
--- | ---
#### Wearable Hearing Aids
V5245 | Hearing aid, digitally programmable, analog, monaural, ITC
V5246 | Hearing aid, digitally programmable analog, monaural, ITE (in the ear)
V5247 | Hearing aid, digitally programmable analog, monaural, BTE (behind the ear)
V5248 | Hearing aid, analog, binaural, CIC
V5249 | Hearing aid, analog, binaural, ITC
V5250 | Hearing aid, digitally programmable analog, binaural, CIC
V5251 | Hearing aid, digitally programmable analog, binaural, ITC
V5252 | Hearing aid, digitally programmable, binaural, ITE
V5253 | Hearing aid, digitally programmable, binaural, BTE
V5254 | Hearing aid, digital, monaural, CIC
V5255 | Hearing aid, digital, monaural, ITC
V5256 | Hearing aid, digital, monaural, ITE
V5257 | Hearing aid, digital, monaural, BTE
V5258 | Hearing aid, digital, binaural, CIC
V5259 | Hearing aid, digital, binaural, ITC
V5260 | Hearing aid, digital, binaural, ITE
V5261 | Hearing aid, digital, binaural, BTE
V5262 | Hearing aid, disposable, any type, monaural
V5263 | Hearing aid, disposable, any type, binaural
V5267 | Hearing Aid or assistive listening device/supplies/accessories, not otherwise specified (Note: For plans that cover hearing aids, this code requires manual review to determine what the item is before a coverage determination can be made.)
V5298 | Hearing aid, not otherwise classified

### DESCRIPTION OF SERVICES

Hearing aids are electronic amplifying devices designed to bring sound more effectively into the ear. A hearing aid consists of a microphone, amplifier and receiver. Wearable hearing aids, including air-conduction hearing aids (ACHAs), are the standard treatment for hearing loss that cannot be medically or surgically corrected.

Semi-implantable electromagnetic hearing aids use the periodic attraction and repulsion of two magnetic fields, one electromagnetic and the other static magnetic, to cause vibration of the ossicles and transmission of sound to the inner ear. When the external sound processor receives sound, it is transformed into electrical signals, which are then amplified and transmitted to a magnetic device that is surgically implanted into the middle ear. The implant's vibrations directly drive the ossicles' movement, producing amplified sound perception. By mimicking the natural vibrations of the ossicular chain, an enhanced signal is sent to the cochlea, resulting in a clearer sound that can be increased without the volume amplification required by ACHAs. In addition, since the air pressure on each side of the sound processor is the same, the wearer does not experience the feeling of occlusion that is common with standard hearing aids. Currently, there are three commercially available semi-implantable electromagnetic hearing devices: 1) the Vibrant™ Soundbridge™ System (Symphonix Devices Inc.; later acquired by Med-El GmbH), 2) the Maxum™ System (Ototronix) that was originally called the Soundtec Direct System, and 3) the Middle Ear Transducer (MET) Ossicular Stimulator System (Otologics LLC). The Soundtec Direct device was voluntarily removed from the market in 2004 while the manufacturer attempted to eliminate a rattling sound some patients experienced, primarily when the sound processor was not used. The Maxum System represents an upgrade over the Soundtec Direct System. The two systems use the same technology and components, although the designs differ.

While conductive hearing loss can often be treated with ACHAs, in some cases (e.g., those resulting from the congenital malformation of the external ear canal, pinna and middle ear structures) the use of ACHAs is precluded. In these cases, a standard bone conducting hearing aid (BCHA) is required. A bone-anchored hearing aid is an alternative to a standard BCHA. The bone-anchored hearing aid is a percutaneous BCHA involving the surgical implantation of a titanium screw into the mastoid process of the skull (osseointegration). In contrast to traditional BCHAs, bone-anchored hearing aids transmit sound vibrations directly to the skull instead through the skin. After a waiting period to allow for complete osseointegration, a sound processor is linked to the skull through an abutment attached to the osseointegrated screw.
Bone conduction hearing aids are used in very young children who are not candidates for air conduction hearing aids. Bone conduction hearing aids are comprised of a bone conduction transducer held in place by a steel spring band over the head or a headband. A potential alternative to conventional bone conduction hearing aids are bone-anchored hearing aids held in place by a headband, with the amplified vibrational sound transmitted transcutaneously to the bones of the skull for transmission to the cochlea. In this application there is no implantation surgery; rather, the sound processor is attached firmly to the head using either a hard or soft headband, and the amplified vibrational sound is transmitted transcutaneously to the bones of the skull for transmission to the cochlea. Children may use a headband until their temporal bone is mature enough for implantation of a bone anchored hearing aid. For adults, a headband is often used to determine whether they might benefit from bone conduction hearing technology.

Semi-implantable electromagnetic hearing aids and bone-anchored hearing aids are classified by the U.S. Food and Drug Administration (FDA) as hearing aids.

Partially implantable transcutaneous bone conduction hearing aids using magnetic coupling such as the Sophono® Otomag Alpha 1 System, the Sophono Alpha 2 MPO™ Magnetic Bone Conduction Hearing System, and the BAHA® Attract System, feature completely subdermal magnetic implants and do not require an abutment. Rather, the external sound processor is attracted by the magnetic implant and rests on top of the skin.

Totally implantable hearing systems are also being evaluated in patients with hearing loss. The Esteem prosthetic hearing restoration device (Envoy Medical Corporation) is totally implanted behind the outer ear and in the middle ear. Unlike hearing aids, the Esteem device does not use a microphone or a speaker. Three implanted components comprise the system: a sound processor, a sensor and a driver that converts electrical signals transmitted by the sound processor to the inner ear, where they are perceived as sound. The device is powered with a maintenance-free battery that may last up to nine years and requires no recharging. The Carina Fully Implantable Hearing Device (Otologics, LLC) is a totally implantable active middle ear device that was in development but does not have FDA approval.

The SoundBite™ Hearing System is a non-surgical intraoral bone conduction hearing aid that was developed for individuals with single-sided deafness. It consists of a behind the ear device (which houses the receiver, wireless transmitter, and microphone) and a removable, custom-fit oral retainer-like device. According to the manufacturer, the device allows sound to travel via the teeth, through the bones, to both cochleae, bypassing the middle and outer ear. As of January 1, 2015, Sonitus Medical, Inc. is no longer manufacturing the Soundbite Hearing System. There is no new information concerning production of this or a similar device.

The Earlens Contact Hearing Device (CHD) is a novel hearing device that uses light to transmit sound, unlike traditional hearing aids that simply amplify air-conducted sound. The Earlens CHD consists of 2 components: a light-based behind-the-ear (BTE) sound processor; and a removable, custom-made tympanic membrane transducer, which is nonsurgically placed deep in the ear canal. The BTE processor uses a microphone and a digital signal processor to pick up sound and convert it to infrared light. Light pulses are transmitted to the transducer and are converted into vibrations that are directly applied to the tympanic membrane and perceived as sound. The Earlens CHD was cleared by the FDA via the de novo regulatory pathway. The de novo process provides a pathway to classify low- to moderate-risk devices for which general controls or general and special controls provide reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

**CLINICAL EVIDENCE**

**Semi-Implantable Electromagnetic Hearing Aids**

Butler et al. (2013) conducted a systematic review to evaluate the effectiveness of the active middle-ear implant in patients with sensorineural hearing loss, compared with external hearing aids. Fourteen comparative studies were included. Nine studies reported on the primary outcome of functional gain: one found that the middle-ear implant was significantly better than external hearing aids, while another found that external hearing aids were generally significantly better than middle-ear implants. Six of the seven remaining studies found that middle-ear implants were better than external hearing aids, although generally no clinically significant difference (i.e., ≥ 10 dB) was seen. The authors concluded that the active middle-ear implant appears to be as effective as the external hearing aid in improving hearing outcomes in patients with sensorineural hearing loss.

**Totally Implantable Hearing Systems**

As part of the premarket approval process, the U. S. Food and Drug Administration (FDA) reviewed a pivotal trial that evaluated Esteem versus pre-implant hearing aids. A total of 60 subjects were implanted with the Esteem and acted as their own controls (using hearing aids prior to implanting the Esteem device). Among the 57 patients with follow-up information, the most frequent adverse event was taste disturbance (42%); facial numbness or paralysis was reported in 7%. Severe adverse device effects were reported in six individuals (10.5%); three patients had revision procedures.
due to limited benefit (not included in the 4 and 10 month evaluations), one had an incision site infection, one had incisions breakdown, and one experienced severe pain and facial weakness. At 4 months the mean decrease in the Speech Reception Threshold was 10.6 dB with 95% confidence interval (CI) of 7.1 to 14.2; at 10 months the mean decrease was 11.4 with 95% CI of 7.7 to 15.2. These changes were considered clinically significant. At 4 months, the Word Recognition Scores were as good as or better in 93% of subjects; however, at 10 months these scores decreased to 88%. As a condition of FDA approval, Envoy Medical must conduct longer-term studies of the device's safety and effectiveness. See the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf9/P090018b.pdf. (Accessed July 10, 2017)

In a systematic review, Pulcherio et al. (2014) reviewed the outcomes of the fully implantable middle ear devices Carina and Esteem for treatment of hearing loss. Twenty-two studies and two literature reviews in English directly demonstrating the results of Carina and Esteem were included in the review. There were a total of 244 patients ranging from 18 to 88 years. One hundred and ten patients were implanted with Carina and with 134 Esteem. There were registered 92 males and 67 females. Five studies provided no information about patients' age or gender. From the data available, the follow-up ranged from 2 to 29.4 months. The comparison of the results about word recognition is difficult as there was no standardization of measurement. The results were obtained from various sound intensities and different frequencies. The outcomes comparing to conventional hearing aids (HAs) were conflicting. Nevertheless, all results comparing to unaided condition showed improvement and showed a subjective improvement of quality of life. According to the authors, the use of fully implantable middle ear devices (MED) is promising for those dissatisfied with their current conventional air-conduction hearing aids. The authors concluded that due to the relatively few publications available and small sample sizes, one must be careful in extrapolating these results to a broader population. Additionally, none of these studies represented level high levels of evidence (i.e., randomized controlled trials).

Klein et al. (2012) conducted a review to examine the safety and effectiveness of fully implantable middle ear devices in the treatment of hearing loss. Thirty articles were selected for full review, of which, 7 articles on the Esteem (n=105 patients) and 13 on the Carina (n=68 patients) met the study's eligibility criteria. Because of heterogeneity across studies, meta-analysis was not performed, and comparisons were made by structured review. The majority of studies were quasi-experimental, pre-post comparisons of aided and unaided conditions. Complication rates with the Esteem were higher than with the Carina. The most common adverse effects with the Esteem were chorda tympani nerve damage or taste disturbance, occurring in 30 percent of patients. Facial weakness was also reported in eight percent of the patients and was permanent in two patients. Seven explants and five revision surgeries were reported with the Esteem device. Device failure was common with the Carina, predominately related to charging difficulties. For both devices, clinically significant improvements in functional gain, speech reception, and speech recognition over the unaided condition were found. In studies comparing the Esteem or Carina to hearing aids, findings were mixed. Although improvements in functional gain were similar to those for hearing aids, speech recognition and quality of life were greater with the implants. According to the authors, despite limited evidence, these devices seem to offer a relatively safe and effective treatment option, particularly for patients who are physically unable to wear conventional hearing aids.

**Partially Implantable Bone Conduction Hearing Aid with Magnetic Coupling**

Dimitriadis et al. (2016) conducted a systematic review of the indications, surgical technique and audiological, clinical and functional outcomes of the BAHA Attract which is a transcutaneous bone conduction hearing aid device. Ten studies and 89 reported cases were included in the review. The vast majority of implanted patients were satisfied with the aesthetics of the device scoring highly at the Abbreviated Profile of Hearing Aid Benefit, Glasgow Benefit Inventory and Client Oriented Scale of Improvement. Overall, hearing outcomes, tested by various means including speech in noise, free field hearing testing and word discrimination scores showed a significant improvement. Complications included seroma or hematoma formation, numbness around the area of the flap, swelling and detachment of the sound processor from the external magnet. The authors concluded that the functional and audiological results presented so far in the literature have been satisfactory and the complication rate is low compared to the skin penetrating Bone Conduction Devices. According to the authors, further robust trials are needed to study the long-term outcomes and any adverse effects.

Denoyelle et al. (2015) evaluated the gain and cutaneous tolerance of the Sophono Alpha1 implant, used for unilateral hearing rehabilitation in children with ear atresia to demonstrate non-inferiority compared to the referral closed skin device, BAHA® on a test-band. Fifteen children included in this prospective clinical trial. Patients’ ages ranged from 61 to 129 months. Sophono Alpha1 demonstrated non-inferiority compared to BAHA on a test-band. At M12, mean aided ACPTA was 2.94dB higher but the mean SRT variation was not significantly different. At M12, all children used the implant 5 to 12h daily without cutaneous complications. Both children and parents reported being satisfied or very satisfied. The score for 7/10 questions in silence or noisy environment was statistically improved when wearing the device. According to the investigators, this prospective study demonstrated non inferiority, good cutaneous tolerance, satisfaction of children and parents and improvement of the quality of life with the Sophono Alpha1 compared to BAHA.
on a test-band. The study population in this study is small, so drawing firm conclusions about the relative performance of these devices is not possible.

Hol et al. (2013) compared a transcutaneous bone conduction hearing aid, the Sophono Alpha 1, with the percutaneous BAHA system in 12 pediatric patients, ranging in age from 5 to 12 years, with congenital unilateral conductive hearing loss. The skin reactions were comparable between both groups and the users received audiologic benefits from both systems. The BAHA-based outcome was slightly better compared with Sophono-based results in sound field thresholds, speech recognition threshold, and speech comprehension at 65 dB. Using a skull simulator, output was 10 to 15 dB lower with the partially implantable device than the BAHA device. The authors concluded that the Sophono offers appealing clinical benefits of transcutaneous bone conduction hearing; however, the audiologic challenges of transcutaneous application remain, as the Sophono does not exceed percutaneous application regarding audiologic output.

Siegert and Kanderske (2013) evaluated the clinical and audiologic results of a partially implantable magnetic bone conduction hearing device without a percutaneous abutment in patients with unilateral or bilateral congenital aural atresia. Twenty-one patients who were implanted due to congenital atresia participated in this follow-up study. The follow-up period was 19.3 ± 12.2 months, with a range of 0.2 to 46.6 months. The average age of the patients at the time of implantation was 12.4 years with a wide range from 6.0 to 50.0 years. The average hearing gain was 31 ± 8 dB, and the suprathreshold word recognition tests increased by 57% ± 23%. Strength of the magnetic force that the patients had chosen themselves measured 0.9 ± 0.4 N with a range from 0.3 to 1.8 N. Skin thickness over the implants measured sonographically was 3.9 ± 0.8 mm (range, 2.5–5.6 mm). According to the authors, this new bone conducting hearing device could be a valuable alternative to other conventional or percutaneous bone conducting hearing solutions. This is an uncontrolled study with a small sample size.

Siegert (2011) evaluated a partially implantable bone conduction hearing aid without a percutaneous abutment (Otomag Bone Conduction Hearing System). The principle of these bone conduction hearing aids is a magnetic coupling and acoustic transmission between implanted and external magnets. Except for temporary pressure marks in 4% of patients, which healed after carefulshimming of the external base plate, there were no other complications. According to the authors, the holding strength of the external components is equivalent to partially implantable hearing aids and cochlea implants and the hearing improvement is similar to other bone conduction hearing aids. The authors found that the comfort and safety of this system is significantly improved compared to conventional or percutaneous bone conduction hearing aids. The lack of a control group limits the validity of the results of this study.

There is insufficient evidence to conclude that partially implantable bone conduction hearing aids using magnetic coupling are beneficial for patients with hearing loss. Additional studies with larger populations and long-term follow-up are needed to evaluate improvement of hearing with these devices.

**Bone-Anchored Hearing Aids (BAHAs)**

The majority of the evidence came from clinical studies at the Nijmegen University Hospital (the Netherlands) and the Birmingham Osseointegration Program (United Kingdom). The largest patient group was included in the Birmingham osseointegration program (McDermott et al., 2002a; Dutt et al., 2002a; Dutt et al., 2002b; McDermott et al., 2002b). The program began in 1988 and by summer 2002 included 351 patients receiving the bone-anchored hearing aid including 242 adults and 109 children. A second prospective study of 84 adult patients aimed at comparing disability, handicap, and benefit of conventional hearing aids versus bone-anchored hearing aid using two instruments, the Glasgow HA benefit profile (GHABP) and the Glasgow HA difference profile (GHADP) (McDermott et al., 2002a). Bone-anchored hearing aid use significantly reduced hearing disability and the patient self-reported benefit and overall satisfaction were improved versus conventional hearing aids.

de Wolf et al. (2011) investigated whether speech perception was better with a bone-anchored hearing aid (BAHA) than with a digital behind-the-ear (BTE) device and whether the crossover point occurs at an air-bone gap of 25 to 30 dB. Experienced unilateral BAHA users with the latest digital BAHA processors were fitted with a powerful BTE with feedback cancellation. After an acclimatization period of 4 weeks, aided thresholds and speech recognition scores were determined and compared to those recorded previously with the BAHA. To obtain patients' opinions, a disability-specific questionnaire was used. Participants included 16 subjects with bilateral mixed hearing loss. Audiometric and speech recognition data showed similar trends to those described previously, but the crossover point had shifted to an air-bone gap of 30 to 35 dB. In the questionnaire, the BTE was rated higher than the BAHA, except by the patients with an air-bone gap that exceeded an average of 45 dB. The investigators concluded that in patients with mixed hearing loss whose air-bone gap exceeded 35 dB, speech recognition is likely to be better with a BAHA than with a BTE. Therefore, the BAHA should receive greater consideration when mixed hearing loss is combined with a significant air-bone gap, even when there are no contraindications for BTEs.

In a prospective clinical trial, Gluth et al. (2010) longitudinally evaluated short- and long-term subject satisfaction/benefit perception, device usage rates, complication rates, and external device repair rates of bone-
Anchored hearing aid (BAHA) implantation on a cohort of adult subjects with profound unilateral sensorineural hearing loss (PUSHL). The study included 56 adults with PUSHL, 21 of which underwent BAHA implantation (followed for an average of 3.2 years after implantation). There were statistically significant improvements in nearly all measures of benefit perception documented as well as a high rate of long-term device usage (81%). Although satisfaction and benefit perception outcomes generally tended to regress over time when compared with initial short-term outcomes, long-term scores still tended to be significantly improved nevertheless as compared with preoperative levels. Approximately 38% of implants experienced severe local skin reactions (Grade 2 and above) around the implant site at some point throughout the follow-up period, whereas only one (4.8%) required implant removal. 66.7% of subjects required repair of their external sound processor. According to the investigators, BAHA implantation provides a high level of short- and long-term perceived benefit and satisfaction in subjects with PUSHL and high rate of long-term device usage. However, implant site adverse local skin reactions and repairs of the external sound processor were common.

Zeitler et al. (2012) evaluated objective hearing outcomes in patients undergoing bone-anchored implantation (BAI) for single-sided deafness (SSD) with residual hearing in the implanted ear. Patients were divided into 2 groups: (1) residual hearing in the affected ear (≤90 dB hearing level pure-tone average) and (2) profound hearing loss in the affected ear (>90 dB hearing level pure-tone average). Patients in both groups showed significant improvement in all objective hearing measures following implantation, and there were no significant differences in objective hearing outcomes between groups. The authors concluded that individuals with SSD and residual cochlear reserve can be successfully implanted with BAI, achieving significant improvements in objective hearing measures.

In a prospective trial, Wazen et al. (2010) evaluated the effectiveness of the BAHA system (fitted with the Divino and Intenso processors) in 21 patients with single-sided deafness (SSD) and mild to moderate hearing loss in the better-hearing ear. The patients showed a statistically significant improvement in all measures with the use of the Divino or Intenso processors compared with the unaided situation. Change in hearing, as measured in noise testing word recognition scores, revealed a statistically significant difference between the two aided conditions favoring the Intenso. The Glasgow Benefit Inventory revealed that 91 percent of the patients reported improvement in their quality of life. The investigators concluded that the BAHA system is effective in the rehabilitation of patients with SSD and mild to moderate hearing loss in the only hearing ear.

Baguley et al. (2006) reviewed 4 controlled prospective studies for a meta-analysis. The four studies that were used all attempted to determine the benefit of contralateral BAHA insertion over contralateral routing of signal (CROS) hearing aids, versus no treatment. The authors note that while the U.S. Food and Drug Administration (FDA) has approved the BAHA device as safe for use in individuals with unilateral acquired sensorineural hearing loss, this review was conducted to measure the efficacy of using these devices within this population. The studies showed that there was no significant improvement in auditory localization, however the BAHA device did significantly improve speech discrimination in noise abilities. Subjective data also showed improvement in auditory abilities with the BAHA device over CROS, as well as improvement over no assistance.

Unilateral implantation of a bone-anchored hearing aid is not indicated for complete sensorineural hearing loss in both ears. However, studies of the BAHA device have indicated that when the poorer ear has a speech reception threshold that is beyond that needed to obtain benefit with conventional amplification (typically a speech reception threshold of 70 dB or more OR a word discrimination score of less than 60%) and the better ear has a speech reception threshold of 35 dB or less and a speech discrimination score of 60% or more, the BAHA device provides consistent benefit of an expanded sound field and improved hearing sensitivity. The reason for this, as described by Lin et al. (2006), relates to two phenomena:

- The BAHA patient does not have to wear a mould in the better ear (as part of the CROS system of amplification)
- The transcranial transmission of sound from the BAHA system appears to attenuate sounds outside of the central speech frequencies, thus improving speech recognition in noise.

These observations are also supported in studies by Hol (2005); Newman (2008); and Linstrom (2009).

**Bilateral Fitting of Bone-Anchored Hearing Aids (BAHA)**

Janssen et al. (2012) systematically review the outcomes of bilateral versus unilateral bone-anchored hearing aids (BAHA) for individuals with bilateral permanent conductive hearing loss (CHL). Studies were included if subjects of any age had permanent bilateral CHL and bilateral implanted BAHA. Outcome measures of interest were any subjective or objective audiologic measures, quality of life indicators, or reports of adverse events. Eleven studies met the criteria for data extraction and analysis. All 11 studies were observational. In most studies, comparisons between unilateral and bilateral BAHA were intra-subject. Bilateral BAHA provided audiologic benefit compared to unilateral BAHA (improved thresholds for tones [2 studies], speech in quiet [5 studies] and in noise [3 studies], and improved localization/lateralization [3 studies]) and patients' perceived subjective benefit from bilateral BAHA (3 studies).
Disadvantages of bilateral BAHAs included listening in noise in some conditions (3 studies), presumed additional cost, and presumed increase in adverse event risk.

Colquitt et al. (2011) performed a systematic review to assess the clinical effectiveness of BAHAs for people with bilateral hearing impairment. Nineteen electronic resources were searched from inception to November 2009. Twelve studies were included. Studies suggested audiological benefits of BAHAs when compared with bone-conduction hearing aids or no aiding. A mixed pattern of results was seen when BAHAs were compared to air-conduction hearing aids. Improvements in quality of life with BAHAs were found by a hearing-specific instrument but not generic quality of life measures. Issues such as improvement of discharging ears and length of time the aid can be worn were not adequately addressed by the studies. Studies demonstrated some benefits of bilateral BAHAs. The authors concluded that the available evidence is weak. As such, caution is indicated in the interpretation of presently available data. However, based on the available evidence, BAHAs appear to be a reasonable treatment option for people with bilateral conductive or mixed hearing loss. Further research into the benefits of BAHAs, including quality of life, is required to reduce the uncertainty.

Dun et al. (2010) evaluated clinical data and quality of life questionnaire outcomes in 21 children and young adults with bilateral Bone-Anchored Hearing Aids (BAHAs). In 90%, both BAHAs were being used 7 days a week. Nine children reported that they switched off both BAHAs when the background became too noisy. Bilateral BAHAs provided better hearing quality according to 70%. The Glasgow Children's Benefit Inventory demonstrated subjective overall benefit of +38 (n = 20). The spatial domain of the Speech, Spatial and Qualities of Hearing scale showed a trend toward better spatial hearing with decreasing age at bilateral application. According to the investigators, bilateral BAHAs showed clear benefit in the vast majority of study participants.

Bilateral implantation of a bone-anchored hearing aid is not indicated for complete sensorineural hearing loss in both ears. However, studies of the Baha device have indicated that when the poorer ear has a speech reception threshold that is beyond that needed to obtain benefit with conventional amplification (typically a speech reception threshold of 70 dB or more or a word discrimination score of less than 60%) and the better ear has a speech reception threshold of 35 dB or less and a speech discrimination score of 60% or more, the Baha device provides consistent benefit of an expanded sound field and improved hearing sensitivity. The reason for this, as described by Lin et al. (2006), relates to two phenomena:
- The Baha patient does not have to wear a mould in the better ear (as part of the CROS system of amplification) and
- The transcranial transmission of sound from the Baha system appears to attenuate sounds outside of the central speech frequencies, thus improving speech recognition in noise.

These observations are also supported in studies by Hol (2005); Newman (2008); and Linstrost (2009).

**Non-Implantable Bone-Anchored or Bone Conduction Hearing Aids**

**Bone-Anchored Hearing Aids Utilizing a Headband**

Christensen et al. (2010) conducted a study to compare functional gain at 500, 1000, 2000, and 4000 Hz for infants and children with bilateral conductive hearing loss who were initially fitted with traditional bone-conduction devices then progressed to Baha with Softband and finally to unilateral Baha implants. Study participants included 10 children with bilateral conductive hearing loss due to congenital atresia and/or microtia. Single-factor, repeated analyses of variance were run to examine the amount of functional gain delivered by the various devices as well as the threshold measures with each device at each frequency. Participants in this study showed a statistically significant improvement when using the Baha Softband over traditional bone-conduction hearing aids. An implanted Baha has statistically as much gain as a bone-conduction transducer at all frequencies tested. The investigators concluded that the Baha system is a valid treatment in conductive hearing loss via a Softband or implanted. They conclude that it outperforms the traditional bone-conduction hearing aids and should be used as a first choice in intervention rather than a last option for inoperable conductive hearing loss.

Ramakrishnan et al. (2011) retrospectively reviewed bone-anchored and Softband-held conductive hearing aids in 109 children and young adults. Criteria for the selection of the implanted device or the Softband were not described; however, the authors did note an uneven distribution by mean age, gender, and syndromic co-morbidity. The authors conclude that this population benefits from bone-anchored and Softband-held conductive hearing aids based on mean scores.

Nicholston et al. (2011) determined the benefit of the Baha Softband for infants and children with bilateral conductive hearing loss; and verified the audibility of the speech spectrum for octave frequencies 500 through 4000 Hz. Twenty-five children aged 6 months to 18 years with craniofacial disorders and bilateral conductive hearing loss participated in the study. Participants were consistent, full-time unilateral Baha users with the Baha Compact bone-conduction amplifier coupled to the head via the Softband. Results revealed an improvement in sound field thresholds with Baha amplification for the four octave frequencies. Percentages of thresholds meeting target levels were significant at all
frequencies, exceeding the 80% criterion. According to the investigators, this study demonstrates the benefit of the BAHA in providing audibility of the speech spectrum for infants and children with bilateral congenital conductive hearing loss.

Clinical trials for bone-anchored hearing aids without osseointegration including the use of a headband are limited for the following reason: the headband is used in small, young children with congenital aural atresia who cannot be fitted for standard hearing aids placed in the ear canal and who, for technical reasons, cannot have a bone-anchored hearing aid implanted. Since this condition is rare, a statistically significant study population would be exceedingly difficult to achieve.

**Intraoral Bone Conduction Hearing Aid**

Moore and Popelka (2013) compared the effectiveness of two types of treatment for unilateral hearing loss (UHL), bone-anchored hearing instruments (BAHI) and a dental device (SoundBite). Nine adult BAHI wearers with UHL were included in the study. Either BAHI or SoundBite were worn for 30 days, and then the devices were swapped and the second device was worn for 30 days. Measures included unaided and aided sound-field thresholds, sound localization, and perception of speech in babble. The APHAB questionnaire was administered for each trial period. Mid-frequency aided thresholds were lower for SoundBite than for BAHI. Both devices gave benefits for localization after 30 days, but there was no difference between devices. Speech perception was better for both devices than for unaided listening when the target speech came from the poorer hearing side or in front, and the interfering babble came from the better-hearing side. There was no consistent difference between devices. APHAB scores were better for SoundBite than for BAHI. The authors concluded that speech perception and sound localization were similar for the two types of device, but the SoundBite led to lower aided thresholds and better APHAB scores than the BAHI. The significance of this study is limited by small sample size and short follow-up period.

Murray et al. (2011a) determine the safety and benefit of the SoundBite Hearing System, an intraoral bone conduction device for single-sided deafness (SSD). The study was a multi-center, controlled, nonrandomized, prospective unblinded study of 22 SSD patients wearing the device over a 6-month period. There were no related adverse events or changes in the medical or audiologic findings at the end of the trial compared with the beginning. There were no significant changes in the mean aided thresholds or the mean dental measures at 3 or 6 months compared with pretrial measures. The mean Abbreviated Profile of Hearing Aid Benefit scores showed improvement for the Background Noise, Reverberation, and Ease of Communication subscales and the Global scale at 3 and 6 months. The results of the SSD questionnaire indicated that the vast majority (>90%) of the subjects reported satisfaction and improvement in a variety of areas after wearing the device. The authors concluded that the SoundBite system is safe and continues to provide substantial benefit for SSD patients with continual daily use over a 6-month period. The significance of this study is limited by non-randomization, small sample size, and short follow-up period.

Miller et al. (2011) evaluated 22 SSD patients wearing an intra-oral hearing device who were enrolled in a prospective study for six months. Differences between the device-anchoring teeth and the equivalent contralateral non-device teeth were evaluated with four dental parameters using a paired t-test. Compared to the non-device teeth, the hearing device teeth did not exhibit any increased recession, increased pocket depth, increased root resorption, or increased alveolar bone loss. There was no association between the amount of alveolar support and hearing thresholds. The authors concluded that the intra-oral component of the hearing device did not adversely affect the dental structures of the subjects in this trial. The significance of this study is limited by a small sample size and short follow-up period.

Murray et al. (2011b) determined the efficacy, benefit, and safety of a new in-the-mouth bone conduction device (SoundBite Hearing System) for single-sided deafness (SSD) in a multicenter, controlled, nonrandomized prospective unblinded study of 28 SSD patients wearing the device. The Hearing in Noise Test scores improved an average of -2.5 dB after 30 days, compared with wearing no device. The Abbreviated Profile of Hearing Aid Benefit scores improved for all subjects for the Global and Background Noise subscales and for all but 1 subject for the Reverberation and Ease of Communication subscales. There were no medical, audiologic, or dental complications. According to the authors, the SoundBite system is safe and effective and provides substantial benefit for SSD patients with continual daily use over a 30-day period. Limitations of the study include non-randomization and inadequate follow-up time.

Popelka et al. (2010) evaluated if the SoundBite intraoral bone-conduction device has advantages over existing bone-conduction devices for reducing the auditory deficits associated with single-sided deafness (SSD). According to the authors, auditory performance in a small sample of SSD subjects indicated a substantial advantage compared with not wearing the device. The authors stated that future studies need to involve performance measures on SSD patients wearing the device for longer periods.

In a prospective cohort study, Gurgel et al. (2015) assessed the safety and efficacy of an intraoral bone conduction (IOBC) hearing prosthesis (SoundBite) after 12 months of use. At the end of 6 months and 12 months, patients were asked to complete the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire and SSD questionnaire in
addition to audiometric testing. Eighty-one patients aged 18 years or older with single-sided deafness (SSD) completed the study. Hearing thresholds remained the same throughout the study. APHAB results showed a significant benefit in categories of ease of communication, reverberation, background noise, and global score. The SSD questionnaire showed a high satisfaction among participants, with 93.8% of patients likely to recommend the IOBC. Dissatisfaction was highest with regard to patient's ability to eat with device, with only 55.6% satisfied. No serious adverse events were reported during the study. The authors concluded that the IOBC is a safe and effective alternative to percutaneous osseointegrated hearing implants for patients with SSD. Patient satisfaction and improved hearing benefit are observed after 1 year of using the device. According to the authors, the IOBC significantly benefitted patients in APHAB categories of ease of communication, reverberation, background noise, and the overall global hearing score. The authors stated that the in-the-mouth transducer is the least-liked feature for some patients, particularly with regard to eating; however, the majority of patients are willing to deal with the size of the device for the hearing benefit gained. The lack of a control group limits the validity of the results of this study. Author reported study limitations include the following: 1) Despite the APHAB being a well-validated way to assess the benefit of hearing prosthesis, the questionnaire responses are subjective and subject to bias. 2) When comparisons were made between the 6- and 12-month APHAB results, 65 and 80 patients filled out the two questionnaires, respectively. The 6-month visit was not a required follow-up time, which explains the difference in participation. The study results have some potential to be skewed because of the differential participation at the two time points, but the 6- and 12-month APHAB results were very similar, with no statistically significant differences. 3) A selection bias is also possible in those patients who were willing to participate in the study as well as providers who have incorporated the IOBC into their practice. These patients and providers may feel more strongly for or against the device than more objective users. 4) More than 90% of patients responded that they preferred the device compared with no device and would likely recommend the device. This percentage may be artificially high because nine subjects withdrew from the study secondary to device-related problems and did not complete the evaluation.

There is insufficient evidence to conclude that intraoral bone conduction hearing aids are beneficial for patients with hearing loss. The quality of the studies was low due to small study populations, short follow-up, and lack of randomization and appropriate control groups. Clinical trials comparing the outcomes of this device with other conventional hearing aids are lacking. Additional studies with long-term follow-up are needed to determine safety and efficacy of this device.

**Laser or Light Based Hearing Aids**

Fay et al. (2013) conducted a single site research and development facility feasibility study to assess the safety, stability, and performance of the broad-spectrum, light-based contact hearing device (CHD) on listeners with hearing impairment. Thirteen participants with symmetric mild-to-severe sensorineural hearing impairment had the CHD placed bilaterally, and a custom-molded light-activated tympanic contact actuator (TCA) was placed into each ear by a physician, where it stayed in contact with the umbo and a portion of the medial wall of the ear canal for 4 months. Each CHD was calibrated and programmed to provide appropriate broad-spectrum amplification. The following were measured to characterize system performance as well as the benefits of amplification via the CHD: Aided and pre-TCA-insertion unaided audiometric thresholds (functional gain), maximum gain before feedback, tympanic membrane damping, Reception Threshold for Sentences (RTS), and Abbreviated Profile of Hearing Aid Benefit (APHAB) measurements. Safety was determined through routine otologic examinations. The results of this feasibility study showed the TCAs remained on participants’ ears for an average total of 122 days, without causing signs of inflammation or infection, and there were no serious device-related adverse events. Measured average maximum output of 90 to 110 dB SPL in the range of 0.25 to 10 kHz, average maximum gain before feedback of 40 dB, and functional gain through 10 kHz show extended-bandwidth broad-spectrum output and gain. RTS results showed significant aided improvements of up to 2.8 dB, and APHAB results showed clinically significant aided benefits in 92% of participants (11/12). The authors concluded the safety, stability, and performance demonstrated in this initial 4-month study suggest that the CHD may offer a feasible way of providing broad-spectrum amplification appropriate to treat listeners with mild-to-severe hearing impairment. This is a small feasibility study with only 13 participants. Larger scale, high quality studies are needed to determine clinical utility of laser and light based hearing. This is an uncontrolled study with a small sample size.

**Professional Societies**

**American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)**

The AAO-HNS considers active middle ear implants as appropriate treatment for adults with moderate to severe hearing loss when performed by a qualified otolaryngologist-head and neck surgeon. Based on available literature demonstrating that clinically selected adults receive substantial benefit, implanting active middle ear implants is accepted medical practice in those who benefit from amplification but are unable to benefit from the amplification provided by conventional hearing aids. Use of active middle ear implants, which have been Food and Drug Administration (FDA)-approved for these indications, should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the Food and Drug Administration in the United States and other similar regulatory agencies in countries other than the United States (AAO-HNS, Active Middle Ear Implants Position Statement 2016).
The AAO-HNS considers bone conduction hearing devices, including implantation of a percutaneous or transcutaneous device and use of a bone conduction oral appliance or bone conduction scalp device to be acceptable, and in many cases preferred, procedures in the treatment of conductive or mixed hearing loss and single-sided deafness when performed by a qualified otolaryngologist-head and neck surgeon. Use of these devices, which have been Food and Drug Administration (FDA)-approved for these indications, should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the FDA in the United States and other similar regulatory agencies in countries other than the United States (AAO-HNS, Bone Conduction Hearing Devices Position Statement 2016).

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

**Semi-Implantable Electromagnetic Hearing Aid**

Two semi-implantable, electromagnetic, direct drive, middle ear hearing devices have received FDA approval.

Vibrant® received FDA approval on August 31, 2000. According to the FDA, Vibrant Soundbridge is utilized for providing a useful level of sound perception to individuals via mechanical stimulation of the ossicles.

According to the professional labeling information on the FDA Web site, the selection criteria for Vibrant Soundbridge include the following:
- Adults aged 18 or older
- Audiologic results consistent with moderate to severe sensorineural hearing loss
- Pure tone air conduction threshold levels within the following ranges:
  - 500 Hz: 30-65 dB
  - 1000 Hz: 40-75 dB
  - 1500 Hz: 45-80 dB
  - 2000 Hz: 45-80 dB
  - 3000 Hz: 50-85 dB
  - 4000 Hz: 50-85 dB
- Word recognition score of 50% or better using recorded material
- Normal middle ear anatomy
- Psychologically and motivationally suitable with realistic expectations of the benefits and limitations of the device

See the following website for more information:

Maxum Hearing Implant® was approved by the FDA on September 7, 2001. This device was manufactured initially under the name Soundtec Direct System by Ototronix, and is currently manufactured under the name Maxum Hearing Implant®. According to the professional labeling information on the FDA Web site, the selection criteria for Maxum Hearing Implant® include the following:
- Adults aged 18 or older
- Audiologic results consistent with moderate to severe sensorineural hearing loss
- Patients with a desire for an alternative to an acoustic hearing device
- Patients should have experience with appropriately fit hearing aids

See the following website for more information:

**Bone-Anchored Hearing Aid with Osseointegration**

**BAHA® Devices and other Bone-Anchored Hearing Aid Devices**

In 1995, the FDA granted approval to Nobelpharm USA to market the Branemark Bone-Anchored Hearing Aid (BAHA) System. Note: since 1995, the device was acquired by Entific Medical Systems and then in 2005, it was acquired by Cochlear Corp. The device was approved for adult patients with malformations of the external ear, chronically draining ear, a pure tone threshold hearing loss of ≥ 45 decibels (dB), and/or inability or unwillingness to use an air conduction hearing aid. In 1999, this approval was extended for use in children 5 years of age or older. See the following website for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf/K984162.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/K984162.pdf). (Accessed September 16, 2016)

The indications for the BAHA System have broadened since the initial FDA approval. In 2001, the BAHA system was approved for bilateral implantation. For bilateral implantation of bone-anchored hearing aids, patients must have moderate to severe bilateral symmetrical conductive hearing loss (defined as less than 10 dB difference in average or less than 15 dB in bone-conduction thresholds at 500, 1000, 2000, and 4000 Hz) or mixed hearing loss with average bone conduction thresholds better than 45 dB hearing loss.

In 2002, the BAHA system was approved for single sided deafness (SSD) or unilateral sensorineural hearing loss. According to the FDA, the use of BAHA hearing aid for SSD is intended to improve speech recognition. The SSD indication for BAHA hearing aid is intended for patients who suffer from unilateral sensorineural deafness on one ear while the other ear has normal hearing. Normal hearing is defined as PTA AC threshold equal to or better than 20dB.
measured at 0.5, 1, 2 and 3 kHz. Baha for SSD is also indicated for patients who are indicated for an AC Contra-lateral Routing Of Signals (CROS) but who for some reason cannot or will not use an AC CROS. See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf2/k021837.pdf. (Accessed September 16, 2016)

BAHA system models include the following:

- **BAHA BP100 (2009)**. See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090720.pdf. (Accessed September 16, 2016)
- **BAHA auditory osseointegrated implant system using model B31300 implant and model BA300 abutment (2010)**. See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf10/K100360.pdf. (Accessed September 16, 2016)

In November 2008, the OBC Bone Anchored Hearing Aid System (Oticon Medical) was cleared by the FDA for marketing through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices. See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf8/k082108.pdf. (Accessed September 16, 2016)

In July 2009, the Ponto Pro Bone Anchored System (Oticon Medical) was cleared by the FDA for marketing through the 510(k) process. See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090996.pdf. (Accessed September 16, 2016)

Other bone anchored hearing aid devices have also been approved by the FDA. See the following website for more information (use product code LXB or MAH): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed September 16, 2016)

**Non-Implantable Bone-Anchored Hearing Aids**

In 2000, the FDA approved the Baha headband. The Baha with headband is intended for patients who suffer from moderate to severe conductive hearing losses. Baha with headband may be particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms. See the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K002913. (Accessed September 16, 2016)

In 2009, the FDA approved the Cochlear Baha BP100 sound processor that is intended for use with the Baha auditory osseointegrated implant (for children aged 5 and older, or adults), or with the Baha Headband or Baha Softband (no age limitations) for the following patients and indications:

- Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB HL.
- Bilateral fitting of the BP100 is intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies.
- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e., single-sided deafness or "SSD"). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to .20 dB HL.
- Baha for SSD is also indicated for any patient who is indicated for an air conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090720.pdf. (Accessed September 16, 2016)

In May 2010, the FDA approved the Otomag Alpha 1(S) Sound Processor for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 100dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
• Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear who for some reason will not or cannot use an AC CR05. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB H-IL (measured at 0.5, 1, 2 and 3 kHz).


The SoundBite Hearing System received FDA approval in January 2011 as a bone conduction hearing aid (K100649). The SoundBite prosthetic device is intended for the following patients and indications:

• Patients who are 18 years or older and have moderately severe, severe, or profound sensorineural hearing loss in one ear and normal hearing in the other ear (i.e., single sided deafness or "SSD"). Normal hearing is defined as a pure tone average (PTA) air conduction (AC) hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 25 dB HL.

**Intraoral Bone Conduction Hearing Aid**

Additionally, use of SoundBite is intended for patients with:

• At least two contiguous molar or premolar teeth with no untreated tooth decay. Patients with tooth decay present are to first have restorations before being fitted for Sound Bite;
• Healthy attachment to those teeth with tooth pockets limited to no more than 5mm;
• No mobile teeth;
• Bone loss no greater than a 34% average on the mesial and distal sides of the tooth as measured on X-ray on the teeth on which the device will be worn.

See the following website for more information:

The SoundBite Hearing System (K110831) received clearance on June 21, 2011 (K110831) for a second indication. In addition to the SNHL indication described for K100649, this clearance includes a second indication for patients with conductive hearing loss where the PTA bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) is ≥ 25 dB hearing level. Its components are a BTE microphone unit and an in-the-mouth hearing device. Accessories include a system charger and programming software. (As of January 1, 2015, Sonitus Medical, Inc. ceased operations and are no longer manufacturing the SoundBite Hearing System. There is no new information available concerning production of this or a similar device). See the following website for more information:

**Totally Implanted Hearing System**


According to the FDA, The Esteem is indicated to alleviate hearing loss in patients by replicating the ossicular chain and providing additional gain. The Esteem is indicated for patients with hearing loss that meet the following criteria:

• 18 years of age or older;
• Stable bilateral sensorineural hearing loss;
• Moderate to severe sensorineural hearing loss defined by pure tone average (PTA);
• Unaided speech discrimination test score greater than or equal to 40%;
• Normally functioning eustachian tube;
• Normal middle ear anatomy;
• Normal tympanic membrane;
• Adequate space for esteem implant determined via a high resolution computed tomography (ct) scan; and
• Minimum 30 days of experience with appropriately fit hearing aids.

See the following website for more information:

**Partially Implantable Bone Conduction Hearing Aid with Magnetic Coupling**

The partially implanted Otomag Alpha 1 (M) Bone Conduction Hearing System received FDA approval in May 2011 as a bone conduction hearing aid. See the following website for more information:

The Cochlear BAHA Attract System (Cochlear Americas, Centennial, CO) received FDA approval on November 7, 2013. See the following Web site for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf13/K131240.pdf. (Accessed November 14, 2016)

**Laser or Light Based Contact Hearing Aid**

The Earlens CHD was cleared by the FDA via the de novo regulatory pathway on September 29, 2015. The de novo process provides a pathway to classify low- to moderate-risk devices for which general controls or general and special controls provide reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. The FDA identifies this generic type of device as a tympanic membrane contact hearing aid. According to the FDA, a tympanic membrane contact hearing aid is a prescription device that compensates for impaired hearing. Amplified sound is transmitted by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane. See the following websites for more information:
(Accessed September 19, 2016)

**Additional Products**

- Bone anchored hearing aid devices include but are not limited to the following: BAHA® HC200, HC220, HC300, Classic 300, Compact, Cordelle, Divino™Hearing Aid (Ear Technology Corp.)
- Implantable electromagnetic hearing aids include Vibrant® Soundbridge® (VIBRANT MED-EL Hearing Technology GMBH, Innsbruck, Austria)

**CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**


Medicare does cover cochlear implantation when criteria are met. Refer to the National Coverage Determination (NCD) for [Cochlear Implantation (50.3)](http://www.cms.hhs.gov/manuals/Downloads/bp102c16.pdf). Local Coverage Determinations (LCDs) do not exist at this time.
(Accessed October 5, 2016)

**REFERENCES**


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**Policy History/Revision Information**

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| 07/14/2017| - Updated list of applicable HCPCS codes; changed service type classification for L8692 from "Wearable Hearing Aids" to “Bone Anchored Hearing Aids (BAHA)“ (no change to coverage guidelines)  
- Updated supporting information to reflect the most current reference links |
| 02/01/2017| - Reformatted and reorganized policy; transferred content to new template  
- Updated benefit considerations; added language to indicate laser or light based hearing aids are excluded from coverage in plans that exclude unproven and/or non-medically necessary services  
- Revised coverage rationale:  
  - Replaced references to "U.S. Food and Drug Administration (FDA) approved" |
indications“ with “U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions”

- Added language to indicate:
  - Laser or light based hearing aids (e.g., Earlens Contact Hearing Device) are unproven and not medically necessary for treating hearing loss
  - The evidence assessing the effectiveness of this device is limited; additional studies with larger populations and long-term follow-up are needed to evaluate improvement of hearing with hearing aids that use light to transmit sound

- Updated definitions:
  - Added definition of:
    - Conductive hearing loss
    - Degree of hearing loss
    - Frequency modulation systems (auditory trainers)
    - Mixed hearing loss
    - Sensorineural hearing loss (SNHL)
  - Revised definition of “hearing aids”

- Updated list of applicable HCPCS codes; revised description for L8693
- Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references
- Archived previous policy version 2016T0396P