Implantable Bone Conduction and Bone-Anchored Hearing Aids

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Replaces  7.01.03

*Medicare has a policy.

Policy

Unilateral or bilateral fully or partially implantable bone conduction (bone-anchored) hearing aid(s) may be considered medically necessary when the following criteria are met.

Unilateral Conductive or Mixed Hearing Loss
Unilateral implantable bone conduction (bone-anchored) hearing aid may be considered medically necessary as an alternative to an air-conduction hearing aid in patients 5 years of age and older with a conductive or mixed hearing loss when ONE of the following medical criteria is met:

- Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear; OR
- Chronic external otitis or otitis media; OR
- Tumors of the external canal and/or tympanic cavity; OR
- Dermatitis of the external canal;

AND the following audiologic criterion is met:

- A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz (same as 500, 1,000, 2,000, and 3,000 Hz) of better than or equal to 45 dB (OBC and BP100 devices), 55 dB (Intenso™ device) or 65 dB (Cordele II™ device).

Bilateral Conductive or Mixed Hearing Loss
Bilateral implantable bone conduction (bone-anchored) hearing aid(s) may be considered medically necessary as an alternative to an air-conduction hearing aid in patients 5 years of age and older when the following criteria are met:

- A symmetrically conductive or mixed hearing loss is present as defined by:
  o A difference between left and right side bone conduction threshold of less than 10 dB on average measured at 0.5, 1, 2 and 3 kHz (same as 500, 1,000, 2,000, and 3,000 Hz) (4 kHz for OBC and Ponto™ Pro devices), OR
  o Less than 15 dB at individual frequencies;

AND the following audiologic criterion is met:

- A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz of better than or equal to 45 dB (OBC and BP100 devices), 55 dB (Intenso™ device) or 65 dB (Cordele II™ device).

Single-sided Sensorineural Deafness and Normal Hearing in the Other Ear
An implantable bone-conduction (bone-anchored) hearing aid may be considered medically necessary as an alternative to a contralateral routing of sound (CROS) air-conduction hearing aid in patients 5 years of age and older with single-sided sensorineural deafness and normal hearing in the other ear.

- The pure tone average air-conduction threshold of the normal ear should be better than 20 dB measured at 0.5, 1, 2, and 3 kHz.

**Non-implanted Use of Bone-conduction (bone-anchored) Hearing Aids**

A bone conduction hearing aid sound processor held against the skull with a softband or headband may be considered medically necessary in children under 5 years of age when the conductive or mixed hearing loss criteria (see above) is met, as an alternative to an air conduction hearing aid. The non-implanted use of the bone conduction sound processor may be used as a pre-surgical trial in children under 5 years of age. (See Benefit Application).

**Other Uses of implanted bone-conduction/bone-anchored hearing aids**

The use of implantable bone-conduction (bone-anchored) hearing aids is considered investigational when criteria are not met, including use in patients with bilateral sensorineural hearing loss.

### Related Policies

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.01.528</td>
<td>Hearing Aids (Excludes Implantable Devices)</td>
</tr>
<tr>
<td>7.01.05</td>
<td>Cochlear Implant</td>
</tr>
<tr>
<td>7.01.84</td>
<td>Semi-Implantable and Fully Implantable Middle Ear Hearing Aids</td>
</tr>
</tbody>
</table>

### Policy Guidelines

#### Patient Characteristics

*Implanted bone-conduction (bone-anchored) hearing aid(s)*

Bone-anchored hearing solutions may also be known as osseointegrated hearing implants. Assessing patients prior to surgery for skull bone quality and thickness adequacy will help to ensure stability of the implanted abutment in the bone behind the ear. Additionally, patients (or caregivers) must be trained to properly clean the implanted and external components to prevent infection and safeguard the skin integrity at the site where the sound processor attaches to the skull. Surgical implantation of the bone anchored hearing aid (BAHA®) device is not FDA approved for children younger than 5 years of age.

*Non-implanted use of a bone-conduction (bone-anchored) hearing aid(s)*

Unique clinical circumstances may justify individual consideration for wearing the bone-conduction sound processor on the surface of the skull with a headband or softband before 5 years of age. Consideration for each request for a non-implanted bone conduction device should be based on a clinical review of applicable medical records to verify the medical necessity criteria listed in this policy are met. (See Benefit Application).

#### Reasonable Useful Life Expectancy for BAHA Parts

<table>
<thead>
<tr>
<th>Replacement Parts</th>
<th>Life Expectancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batteries</td>
<td>72 per 6 months</td>
</tr>
<tr>
<td>Headband</td>
<td>1 per year</td>
</tr>
<tr>
<td>Processor</td>
<td>1 per 5 years</td>
</tr>
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</table>

Adapted from Wisconsin Department of Health Services, 2005, [https://www.forwardhealth.wi.gov/kw/archive/DMS040116.pdf](https://www.forwardhealth.wi.gov/kw/archive/DMS040116.pdf), page 90.
**Coding**

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
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<tbody>
<tr>
<td>69710</td>
<td>Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone</td>
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<tr>
<td>69711</td>
<td>Removal or repair of electromagnetic bone conduction hearing 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>
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<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>
<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>
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**HCPCS**

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<th>Code</th>
<th>Description</th>
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<tr>
<td>L8690</td>
<td>Auditory osseointegrated device, includes all internal and external components</td>
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<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>
<tr>
<td>L8695</td>
<td>External recharging system for battery (external) for use with implantable neurostimulator, replacement only</td>
</tr>
</tbody>
</table>

**Note:** Cochlear implants, used for the treatment of severe to profound deafness are addressed in a separate medical policy. (See Related Policies)

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**Description**

Sensorineural, conductive and mixed hearing loss may be treated with various devices, including conventional air-conduction (AC) or bone-conduction external hearing aids. AC hearing aids may not be suitable for patients with chronic middle ear and ear canal infections, atresia of the external canal, or an ear canal that cannot accommodate an ear mold. Bone-conduction hearing aids may be useful for individuals with conductive hearing loss, or (if used with contralateral routing of signal), for unilateral sensorineural hearing loss. Implantable, bone-anchored hearing aids (BAHAs) that use a percutaneous or transcutaneous connection to a sound processor have been investigated as alternatives to conventional bone-conduction hearing aids for patients with conductive or mixed hearing loss or for patient with unilateral single-sided sensorineural hearing loss.

In children under 5 years of age the transcutaneous use of the BAHA® has shown positive outcomes in small studies. The bone conduction-type hearing aid is held against the skin behind the ear, or at another bony location of the skull using a strap, headband or softband. The headband is soft plastic while the softband is soft elastic with a plastic disc-like snap connector either modeled or sewn into the band. A BAHA® sound processor is attached to the plastic connector and the band/headband adjusted to the size of the individual's head, secured with a Velcro® fastener (Velcro USA Inc., Manchester, NH). (See Appendix).

**Background**

**Hearing Loss**

Hearing loss is described as conductive, sensorineural, or mixed, and can be unilateral or bilateral. Normal hearing is the detection of sound at or below 20 dB (decibel). The American Speech Language Hearing Association (ASLHA) has defined the degree of hearing loss based on pure-tone average (PTA) detection thresholds as mild (20 to 40 dB), moderate (40 to 60 dB), severe (60 to 80 dB), and profound (equal to or greater than 80 dB). PTA is calculated by averaging the hearing sensitivities (ie, the minimum volume that the patient hears) at multiple frequencies (perceived as pitch), typically within the range of 0.25-8 kHz.

Sound amplification through the use of an air-conduction (AC) hearing aid can provide benefit to patients with sensorineural or mixed hearing loss. Contralateral routing of signal (CROS) is a system in which a microphone on the affected side transmits a signal to an AC hearing aid on the normal or less affected side.
Bone-Conduction Hearing Devices

External bone-conduction hearing aids function by transmitting sound waves through the bone to the ossicles of the middle ear. The external devices must be closely applied to the temporal bone, with either a steel spring over the top of the head or with the use of a spring-loaded arm on a pair of spectacles. These devices may be associated with either pressure headaches or soreness.

A bone-anchored implant system combines a vibrational transducer coupled directly to the skull via a percutaneous abutment that permanently protrudes through the skin from a small titanium implant anchored in the temporal bone. The system is based on osseointegration through which living tissue integrates with titanium in the implant over 3 to 6 months, conducting amplified and processed sound via the skull bone directly to the cochlea. The lack of intervening skin permits the transmission of vibrations at a lower energy level than required for external bone-conduction hearing aids. Implantable bone-conduction hearing systems are primarily indicated for people with conductive or mixed sensorineural or conductive hearing loss. They may also be used with CROS as an alternative to an AC hearing aid for individuals with unilateral sensorineural hearing loss.

A bone conduction processor can also be used with a softband or headband. The sound processor is pressed against the head, usually behind the ear. With this application, there is no titanium peg implantation surgery. The amplified sound is transmitted transcutaneously to the cochlea using the skull bones, bypassing the outer and middle ear. In children under 5 years of age, this non-implanted use of the processor may be part of the trial period before surgery.

Partially implantable magnetic bone-conduction hearing systems, also referred to as transcutaneous bone-anchored systems, are an alternative to the bone-conduction hearing systems connected percutaneously via an abutment. With this technique, acoustic transmission occurs via magnetic coupling of the external sound processor and internally implanted device components. The bone-conduction hearing processor contains magnets that adhere externally to magnets implanted in shallow bone beds with the bone-conduction hearing implant. Since the processor adheres magnetically to the implant, there is no need for a percutaneous abutment to physically connect the external and internal components. To facilitate greater transmission of acoustics between magnets, skin thickness must be reduced to 4-5 mm over the implant when it is surgically placed.

Regulatory Status
There are 6 BAHA® sound processors manufactured by Cochlear Americas (Englewood, CO), that have received 510(k) clearance for marketing from the U.S. Food and Drug Administration (FDA):

- BAHA 5
- BAHA® Cordelle II™
- BAHA® Divino™
- BAHA® Intenso™ (digital signal processing)
- BAHA® BP 100™
- BAHA® 4 (upgraded from the BP 100™)

The FDA cleared the BAHA® system for use in children aged 5 years and older and in adults for the following indications:

- Patients who have conductive or mixed hearing loss and can still benefit from sound amplification;
- Patients with bilaterally symmetric conductive or mixed hearing loss, may be implanted bilaterally;
- Patients with sensorineural deafness in 1 ear and normal hearing in the other (i.e., single-sided deafness, SSD);
- Patients who are candidates for an air-conduction contralateral routing of signals (AC CROS) hearing aid but who cannot or will not wear an AC CROS device.

BAHA® sound processors can also be used with the BAHA® Softband™ without surgery. The non-surgical/transcutaneous application of the BAHA® processor received FDA clearance in 2002 for use in children under the age of 5 years.

Other implantable bone-conduction hearing systems that rely on an abutment and have similar indications as the Cochlear Americas’ BAHA devices include:

A next-generation Ponto Pro device can be used with either Oticon or BAHA implants.

The 2 partially implantable magnetic bone-conduction devices cleared by FDA through the 510(k) process are:
- Otomag® Bone Conduction Hearing System (Sophono, Inc., Boulder, CO, now owned by Medtronic, Minneapolis, MN)
- Cochlear BAHA® Attract (Cochlear Americas, Centennial, CO)

Audiant Bone Conductor (Medtronic Xomed, Inc. Jacksonville, FL) is a type of electromagnetic bone conduction hearing device. This product is no longer actively marketed. However, patients with existing Audiant devices may require replacement, removal, or repair.

The BoneBridge™ (MedEl, Innsbruck, Austria) is a partially-implantable bone-conduction hearing aid that is considered an active transcutaneous device. It is cleared for marketing in Europe but is not FDA approved for use in the U.S.

In 2011, The SoundBite™ Hearing System (Sonitus Medical, San Mateo, CA) is an intraoral bone-conducting hearing prosthesis that consists of a behind-the-ear microphone and an in-the-mouth hearing device was cleared through FDA’s 510(k) clearance process for similar indications as the BAHA. Since this system has no implanted components, it is not addressed in the current policy. As of January 2015, Sonitus Medical ceased operation and no information about production of this device by another company is available.

FDA product code (for bone-anchored hearing aid): LXB

FDA product code (for implanted bone-conduction hearing aid): MAH

**Scope**

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This policy does not apply to Medicare Advantage.

**Benefit Application**

A bone-conduction (bone-anchored) hearing aid is a surgically implantable device to treat a medical condition. The device and implantation surgery should be reimbursed under the medical benefit.

Benefit limitations regarding hearing aids may apply to these devices, specifically when the Implantable Bone-Conduction and Bone-Anchored Hearing Aid (BAHA®) device is used transcutaneously (on the surface of the skin of the head) held in place by a headband or softband and not implanted.

**Rationale**

This policy was created in October 2012 and updated regularly based on searches of the MEDLINE database, most recently through December 2016.

The evidence related to the use of implantable bone-conduction devices, also referred to as bone-anchored hearing aids (BAHA), is characterized by observational studies that report pre-hearing and post-hearing outcomes in patients treated with these devices. Many of these studies combine patients with differing underlying disease
states and indications. No randomized controlled trials (RCTs) have compared implantable bone-conduction hearing aids to other hearing augmentation devices, or sham devices.

However, given the objectively measured outcomes and the largely invariable natural history of hearing loss in individuals who would be eligible for an implantable bone-conduction device, a within-subjects comparison of hearing before and after device placement may be a reasonable study design. Following is a summary of key findings.

**Overall Efficacy of Bone-Anchored Hearing Aids**

**Systematic Reviews**

Two systematic reviews by the Health Technology Assessment Program were published in 2011 on the use of BAHAs for bilateral hearing impairment. The quality of available studies on the use of BAHAs was weak. No studies with control groups were identified. Cohort pre-post studies and cross-sectional comparative studies demonstrated improvements in hearing with use of BAHAs over conventional bone-conduction hearing aids or unaided hearing. However, whether improvements in hearing with BAHAs were greater than with air-conduction (AC) hearing aids was uncertain. Additionally, bilateral use of BAHAs improved hearing outcomes in some patients over unilateral use, but that evidence, too, was uncertain. Implant loss ranged between 6.1% and 19.4%. Reviewers noted that hearing-specific quality of life (QOL) improved, but overall QOL did not differ.

**Observational Studies**

Since the publication of the systematic reviews, a number of observational studies have evaluated specific aspects of BAHA implantation or reported outcomes in specific populations. Several observational studies have suggested that newer-generation BAHAs with fully digital signal processors improve hearing to a greater degree than earlier-generation devices.

In 2014, Farnoush et al. retrospectively compared BAHA placement with reconstruction of the external auditory canal for children and adolescents with congenital aural atresia or stenosis who were treated at a single institution from 1988 to 2011. Sixty-eight patients were included, 49 who underwent external auditory canal reconstruction (EACR) and 19 who received a BAHA. Groups differed significantly in terms of age, presence of bilateral atresia, and presence of an associated syndrome. Audiologic data were available for 41 patients. At short-term (<6 months post-surgery) follow up, the BAHA group had larger hearing gains on air conduction than the EACR group (44.3 dB vs 20.0 dB; P<0.001); similarly, the BAHA group had larger hearing gains at long term (>1 year post-surgery) follow up (44.5 dB vs 15.3 dB; P<0.001). Quality of life scores and requirements for revision surgery did not differ significantly between the groups.

In 2011, Ramakrishnan and colleagues retrospectively reviewed bone-anchored and Softband-held conductive hearing aids in 109 children and young adults in a single center. The patient population was somewhat unique in that many patients had craniofacial or genetic syndromes in addition to hearing loss (22 of 109). 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. Primary measures were the Glasgow Benefit Inventory or Listening Situation Questionnaire (parent version) administered at least 3 months following hearing aid intervention. Mean overall Glasgow Benefit Inventory scores were reported as +29 (range +11 to +72). The mean Listening Situation Questionnaire score of 17 was reported as less than a referral cutoff of 22. The authors conclude that this population benefits from bone-anchored and Softband-held conductive hearing aids based on mean scores. However, the study is limited due to a heterogeneous patient population, a lack of pre-intervention measures, or a controlled comparator group. Other series describing outcomes for pediatric patients treated with bone-anchored devices have also reported a benefit in hearing scores, including den Besten et al (2015) in 79 children aged 17 and under.

Older case series reported patient-reported benefits and patient satisfaction after BAHA placement. Some have suggested that the BAHA improved hearing better than early bone-conducting devices and AC hearing aids and produced acceptable hearing outcomes in individuals unable to receive an AC hearing aid.

**Section Summary**

The available studies on the use of BAHAs are observational pre-post designs without control groups and cross-
sectional comparative studies. Although the study designs were generally weak, in general, use of BAHAs was associated with larger improvements in hearing than conventional nonimplanted bone-conduction hearing devices or unaided hearing. Given the objectively measured outcomes and the largely invariable natural history of hearing loss in individuals who would be eligible for an implantable bone-conduction device, the demonstrated improvements in hearing after device placement are likely attributable to the device.

**Bilateral BAHA Devices in Conductive or Mixed Hearing Loss**

A number of studies, published over several years, have demonstrated a consistent improvement in speech recognition in noise and in sound localization with bilateral devices in conductive or mixed hearing loss.

Janssen et al. (2012) conducted a systematic review to assess the outcomes of bilateral versus unilateral BAHA for individuals with bilateral permanent conductive hearing loss (CHL). (14) Their search strategy included studies of all languages published between 1977 and July 2011. Studies were included if subjects of any age had permanent bilateral CHL and bilateral implanted BAHAs. Outcome measures of interest were any subjective or objective audiologic measures, quality of life indicators, or reports of adverse events. Eleven studies met their inclusion criteria. All 11 studies were observational. There were a total of 168 patients in the 11 studies, 155 of whom had BAHAs and 146 of whom had bilateral BAHAs. In most studies, comparisons between unilateral and bilateral BAHA were intra-subject. Patients ranged from 5 to 83 years of age; 46% were male, and 54% were female. Heterogeneity of the methodologies between studies precluded meta-analysis, therefore a qualitative review was performed. Results from 3 of 11 studies were excluded from synthesis because their patients had been included in multiple publications. Adverse events were not an outcome measure of any of the included studies. (14) In general, bilateral BAHA was observed to provide additional objective and subjective benefit compared to unilateral BAHA. For example, the improvement in tone thresholds associated with bilateral BAHA® ranged from 2-15dB, the improvement in speech recognition patterns ranged from 4-5.4dB, and the improvement in the Word Recognition Score ranged from 1-8%. However, these results were based on a limited number of small observational studies consisting of heterogeneous patient groups that varied in age, severity of hearing loss, etiology of hearing loss, and previous amplification experience.

Examples of individual studies include the following. In 2001, Bosman et al reported on 25 patients who were using bilateral devices. (15) They found that both speech recognition in noise and directional hearing improved with the second device. Priwin et al (2004) reported similar findings in 12 patients with bilateral devices. (16) A 2005 consensus statement concluded that bilateral devices resulted in binaural hearing with improved directional hearing and improved speech-in-noise scores in those with bilateral CHL and symmetric bone-conduction thresholds. (17) A number of other studies cited in the 2005 consensus statement found benefits similar to those noted by Bosman and by Priwin. (15, 16) Positive outcomes continue to be reported: Dun et al (18) identified improvements in the Glasgow Benefit Inventory in 23 children, while Ho et al in 2009 (19) reported the same benefit in 93 adults.

**BAHA Devices for Unilateral Sensorineural Hearing Loss**

In 2015, Peters et al reported results from a systematic review of studies comparing BAHA devices with contralateral routing of signal (CROS) systems to hearing aids with CROS for single-sided deafness (SSD). (20) Six studies met eligibility criteria, including 1 RCT and 3 prospective and 2 retrospective case series, 5 of which were considered to have moderate-to-high directness of evidence and low-to-moderate risk of bias. The 5 studies (n=91 patients) with low or moderate risk of bias; they were noted to have significant heterogeneity in the populations included. For speech perception in noise, there was no consistent improvement with aided hearing over unaided hearing in all environments. All studies reported equal sound localization and QOL outcomes for both hearing conditions.

Baguley et al. (2006) reviewed the evidence for contralateral BAHAs in adults with acquired unilateral sensorineural hearing loss. (21) None of the four controlled trials reviewed showed a significant improvement in auditory localization with the bone-anchored device. However, speech discrimination in noise and subjective measures improved with these devices; for these parameters, the BAHAs resulted in greater improvement than that obtained with the conventional air-conduction contralateral routing of signal (CROS) systems.

Since publication of the Peters systematic review, 2 prospective, interventional studies have compared patient outcomes with transcutaneous BAHA devices to CROS hearing aids for SSD. Leterme et al (2015) assessed 24 adults with SSD, 18 of whom were evaluated with trials of both hearing aids with CROS and bone conduction–assisted hearing using the Baha Softband. (22) Most (72%) patients, after completing trials of both devices,
preferred the BAHA device to hearing aids with CROS. Glasgow Benefit Inventory and Abbreviated Profile of Hearing Aid Benefit (APHAB) scores did not differ significantly between devices. Sixteen of the 18 subjects elected to undergo implantation of a percutaneous BAHA device. In general, hearing improvement with the Baha Softband trial correlated with hearing improvements following device implantation. Snapp et al (2017) reported a prospective single-center study of 27 patients with unilateral severe-profound sensorineural hearing loss who had either a CROS (n=13) or transcutaneous BAHA (n=14) device.(23) Mean device use was 66 months for the BAHAs and 34 months for CROS devices. Both BAHA and CROS groups had significant improvement in speech-in-noise performance, but neither showed improvement in localization ability. There were no differences between the devices for subjective measures of posttreatment residual disability or satisfaction as measured by the Glasgow Hearing Aid Benefit Profile (GHABP).

Several centers have reported on findings from observational studies that evaluated the benefits of BAHAs for patients with unilateral sensorineural hearing loss (SSD). Most were retrospective. Studies representative of this group are described next.

Zeitler et al. (2012) reported on a retrospective case series of 180 patients with SSD and residual hearing in the implanted ear who underwent unilateral or bilateral BAHA placement at a university medical center in the United States.(24) Significant improvement was reported in objective hearing measures (speech-in-noise and monosyllabic word tests) following BAHA implantation. Subjective benefits from BAHAs varied across patients based on results from the Glasgow Hearing Aid Benefit Profile (GHABP), but patients with residual hearing in the affected ear tended toward improved satisfaction with their device postoperatively.

Additional series from various countries, with sample sizes ranging from 9 to 145 patients, have reported on outcomes after implantation of BAHAs for SSD. In general, studies have indicated improvements in patient-reported speech quality, speech perception in noise, and patient satisfaction.(25-32)

**Section Summary**

Single-arm case series with sample sizes ranging from 9 to 180 patients have generally reported some improvements in patient-reported outcomes after implantation of bone conduction devices, but no improvements in speech recognition or hearing localization. However, in studies with comparators, outcomes for patients with bone-anchored devices were similar to those for patients with hearing aids with CROS.

**BAHA Devices in Children Younger than Five Years of Age**

The BAHA device has been investigated in children younger than 5 years in Europe. Reports have described experiences with preschool children or children with developmental issues that might interfere with device maintenance and skin integrity. A 2-stage procedure may be used in young children. In the first stage, the fixture is placed into the bone and allowed to fully develop osseointegration. After 3-6 months, a second procedure is performed to connect the abutment through the skin to the fixture.(32)

The largest series in children under 5 years identified for this review, described by Amonoo-Kuofi et al (2015), included 24 children identified from a single center’s prospectively maintained database.(33) Most patients underwent a 2-stage surgical approach. Most patients (52%) received the implant for isolated microtia or Goldenhar syndrome (16%). Following implantation, 13 patients (54%) had grade 2 or 3 local reactions assessed on the Holgers Scale (redness, moistness, and/or granulation tissue) and 7 (29%) had grade 4 local reactions on the Holgers Scale (extensive soft-tissue reaction requiring removal of the abutment). Quality of life scores (Glasgow Children’s Benefit Inventory [GCBI]; scoring range, -100 to 100) were obtained in 18 subjects/parents, with a final mean score change of +40 points. Audiologic testing indicated that the average performance of the device fell within the range of normal auditory perception in noisy and quiet environments.

Marsella et al. (2012) reported on a single-center experience in Italy with pediatric BAHAs from the inception of their program in 1995 to December 2009.(34) A total of 47 children (21 females and 26 males) were implanted, 7 were younger than 5 years. Functional gain was significantly better with BAHA than conventional nonimplanted bone-conduction hearing aids and there was no significant difference in terms of functional outcome between the 7 younger patients than the rest of the patient cohort. Based on these findings, the study authors suggest that implantation of children at an age younger than 5 years can be conducted safely and effectively in such settings. () The report conclusions were limited by the small number of very young children in the sample and the limited statistical power to detect a difference between younger and older children.
Davids et al. (2007) provided BAHA devices to children younger than 5 years of age for auditory and speech-language development and retrospectively compared surgical outcomes for a study group of 20 children 5 years or younger and a control group of 20 older children. (35) Children with cortical bone thickness greater than 4 mm underwent a single-stage procedure. The interstage interval for children having 2-stage procedures was significantly longer in the study group in order to allow implantation in younger patients without increasing surgical or postoperative morbidity. Two traumatic fractures occurred in the study group versus 4 in the older children. Three younger children required skin site revision. All children were wearing their BAHA devices at time of writing.

McDermott et al. (2008) reported on the role of bone anchored hearing aids in children with Down syndrome in a retrospective case analysis and postal survey of complication rates and quality of life outcomes for 15 children aged 2 to 15 years. (36) All patients were using their BAHA® devices after follow-up of 14 months. No fixtures were lost; skin problems were encountered in 3 patients. All 15 patients had improved social and physical functioning attributed to improved hearing.

**Section Summary**
There are few data on use of BAHA devices in children younger than 5. Three case series with a total of fewer than 60 children younger than 5 years have reported improvements in QOL after implantation with BAHA devices. One comparative observational study, with 7 children younger than 5, reported significantly better improvement in functional gain with BAHAs than with conventional nonimplanted bone-conduction hearing aids in an analysis including all ages.

**Safety and Adverse Events Related to Bone-Anchored Hearing Aids**
In addition to the literature evaluating the effectiveness of BAHA devices in improving hearing, studies have assessed complications with these devices.

**Systematic Reviews**
Verheij et al (2016) published a systematic review on complications of tissue preservation surgical techniques with percutaneous BAHA devices including 18 studies with 381 devices. (37) The implantation techniques reported in the studies were as follows: punch method, 4 studies (81 implants); linear incision technique without soft tissue reduction, 13 studies (288 implants); and Weber technique, 1 study (12 implants). Indications for surgery were SSD (n=68), sensorineural hearing loss (n=4), mixed hearing loss (n=65), or CHL (n=66). The Holgers classification was used to grade soft tissue reactions (grade 0, no reaction; grade 2, red and moist tissue; grade 3, granulation tissue; grade 4, removal of skin-penetrating implant necessary due to infection). The incidence of Holgers 3 was 2.5% with the punch technique, 5.9% with the linear incision technique, and 0% with the Weber technique. Holgers 4 was reported in 1 patient implanted with the linear incision technique.

In 2013, Kiringoda and Lustig reported on a meta-analysis of complications related to BAHA implants. Selected were 20 studies that evaluated complication in 2134 adult and pediatric patients who received a total of 2310 BAHA implants. (38) The quality of available studies was considered poor and lacking in uniformity. Complications related to BAHA implants were mostly minor skin reactions. The incidence of Holgers grade 2 to 4 skin reactions ranged from 2.4% to 38.1% in all studies. The incidence of failed osseointegration was 0% to 18% in adult and mixed population studies and 0% to 14.3% in pediatric population studies. The incidence of revision surgery was 1.7% to 34.5% in adult and mixed population studies and 0.0% to 44.4% in pediatric population studies. Implant loss occurred in 1.6% to 17.4% in adult and mixed population studies and in 0.0% to 25% in pediatric studies.

**Observational Studies**
In 2012, Dun et al. assessed soft tissue reactions and implant stability of 1,132 percutaneous titanium implants for bone conduction devices through a retrospective survey of 970 patients undergoing implants between September 1988 and December 2007 at a University Medical Center in the Netherlands. (39) The study investigators also examined device usage and compared different patient age groups (children, adults, elderly patients) over a 5-year follow-up period. Implant loss was 8%. In close to 96% of cases, there were no adverse soft tissue reactions. Significantly more soft tissue reactions and implant failures were observed in children than in adults and elderly patients (p < 0.05). Implant survival rates were lower in patients without mental retardation (p = 0.001).

In 2010, Hobson et al. reviewed complications on 602 patients at a tertiary referral center over 24 years and compared their observed rates to those published in 16 previous studies. (40) The overall observed complication
rate of 23.9% (144 of 602) is similar to other published studies (complication rate 24.9% + 14.85). The most common complications were soft tissue overgrowth, skin infection, and fixture dislodgement. The observed rate of revision surgery of 12.1% (73 of 602) was also similar to previously published rates of 12.7%. Top reasons for revision surgery were identical to observed complications.

In 2011, Wallberg et al. reported on the status of 150 implants placed between 1977 and 1986 and followed for a mean of 9 years. Implants were lost in a total of 41 patients (27%). Reasons for implant loss were: removal in 16 patients, osseointegration failure in 17 patients, and direct trauma in 8 patients. In the remainder of 132 patients with implant survival, BAHA's were being used by 119 patients (90%) at the end of follow-up. For children, implant complications were even more frequent, as reported by Kraai et al. in a follow-up evaluation of 27 implants placed in children ages 16 years or younger between 2002 and 2009. In this retrospective report, soft tissue reactions occurred in 24 patients (89%); implant removal or surgical revision was required in 10 patients (37%); 24 patients (89%) experienced soft tissue overgrowth and infection; and 7 patients (26%) experienced implant trauma. Chronic infection and overgrowth at the abutment prevented use of the implant in 3 patients (11%).

In 2014, Allis et al. conducted a prospective observational cohort study with a retrospective historical control to evaluate complication rates of skin overgrowth, infection, and the need for revision surgery associated with a BAHA implant with a longer (8.5 mm) abutment. Twenty-one subjects were treated with the 8.5 mm abutment implant from 2011 to 2012 and were compared with 23 subjects treated with a 5.5-mm-abutment implant from 2010 to 2011. Groups were generally similar at baseline, with the exception that the 8.5 mm abutment implant patients were older (62 years vs 48 years, P=0.012). Patients in the longer abutment group were less likely to experience infection (10% vs 43%; P=0.02), skin overgrowth (5% vs 41%; P=0.007), and need for revision (10% vs 45%; p=0.012), respectively.

Other observational cohort studies, ranging in size from 47-974 subjects, have reported safety and adverse effects outcomes after BAHA placement. Across these studies, implant loss ranged from 4% to 18%.

Different surgical techniques for implanting BAHA devices and specific BAHA designs have yielded better safety outcomes. In a 2016 systematic review of 30 articles on the association between surgical technique and skin complications following BAHA implantation, the dermawest technique (vs a skin graft or linear technique) was linked to more frequent skin complications. Fontaine et al. (2014) compared complication rates for 2 BAHA surgical implantation techniques among 32 patients treated from 2004 to 2011. Complications requiring surgical revision occurred in 20% of cases who had a skin flap implantation method (n=20) and in 38% of cases who had a full-thickness skin graft implantation method (n=21; p=0.31). Hultcrantz and Lanis (2014) reported shorter surgical times and fewer cases of numbness and peri-implant infections in 12 patients treated with a non-skin-thinning technique, compared with 24 patients treated with a flap or a dermatome implantation technique. In a comparison of 2 types of BAHA devices, one with a 4.5-mm diameter implant and a rounded 6-mm abutment (n=25) and one with a 3.75-mm diameter implant and a conically shaped 5.5-mm abutment (n=52), Nelissen et al. (2014) reported that implant survival was high for both groups over a 3-year follow-up, although the conically shaped abutment had greater stability. Singam et al. (2014) reported results of a BAHA implantation technique without soft tissue reduction in conjunction with a longer device abutment in 30 patients. Twenty-five patients had no postoperative complications. Five subjects developed postoperative skin reactions, of whom 3 required soft tissue reduction. Roplekar et al. (2016) compared skin-related complications of the traditional skin flap method to the linear incision method performed by a single surgeon in 117 patients with at least 1 year of follow-up. Fifty-two (24%) patients experienced skin-related complications in the skin flap group (12 skin overgrowths, 8 wound infections, 1 numbness) and 3 (10%) patients experienced complications in the linear incision group (3 wound infections).

Section Summary
The quality of available data for adverse events is generally poor with high heterogeneity. The most frequently reported complication from surgical procedures for BAHA insertion are adverse skin reactions, with an incidence of Holgers grade 2 to 4 reactions ranging from less than 2% to more than 34%, and implant loss ranging from less than 2% to more than 17%. There is some evidence of improvement in complication rates and severity with newer surgical techniques such as linear incision.

Partially Implantable Magnetic Bone-Conduction Hearing Aids
A smaller body of literature addresses outcomes associated with transcutaneous, partially implantable bone-
anchored devices that magnetically-couple the sound processor with the implant. Similar to the literature available for percutaneous bone-anchored devices, the majority of studies use a within-subjects comparison of hearing thresholds with and without the device. The indications for partially implantable systems are the same as those for transcutaneous bone-anchored devices.

Prospective Studies
Two prospective studies evaluating different transcutaneous systems were identified. Both trials were small (27 and 15 individuals), but both demonstrated improvements in hearing outcomes.

Briggs et al (2015) reported results of a prospective interventional evaluation of the percutaneous, partially implantable Baha Attract system among 27 adults with a conductive or mild mixed hearing loss in the ear to be implanted. The choice of sound processor was based on patient preference and hearing tests with the use of various sound processors with a Baha Softband prior to device implantation. All 27 patients enrolled received an implant. Sound processor fitting occurred at 4 weeks postimplantation in all but 1 patient. At 9-month follow-up, pure tone audiometry (PTA; mean of 500, 1000, 2000, and 4000 Hz) was significantly improved with the implant and sound processor compared with unaided hearing (18.4 dB HL; SD=6.9 dB; p<0.001). Patients generally showed improvements in speech recognition in noise, although comparing results across test sites is difficult due to different languages and methodologies used for testing speech recognition at each site. Compared with preoperative unaided state, scores on the Abbreviated Profile of Hearing Aid Benefit (APHAB) overall score (p=0.038) and Reverberation (p=0.016) and Background noise (p=0.035) subscales.

Denoyelle et al (2015) reported on a prospective clinical trial of the Sophono device in children aged 5 to 18 years with uni- or bilateral congenital aural atresia with complete absence of the external auditory canal with pure conductive hearing loss. The study included a within-subject comparison of hearing results with the Sophono devices with those obtained with the Baha Softband preoperatively. Fifteen patients were enrolled and implanted (median age, 97 months). At 6-month follow-up, mean aided air-conduction PTA was 33.49 (mean gain, 35.53 dB), with a mean aided sound reception threshold of 38.2 (mean gain, 33.47 dB). The difference in air conduction PTA between the Baha Softband and the Sophono device was 0.6 dB, with a confidence interval upper limit of 4.42 dB, which met the study’s prespecified noninferiority margin. Adverse effects were generally mild, including skin erythema in 2 patients, which improved by using a weaker magnet, and brief episodes of pain or tingling in 3 patients.

Nonrandomized Comparative Studies
A limited amount of data is available comparing transcutaneous with percutaneous bone-anchored conduction devices. In 2013 Hol et al. reported on a comparison of Baha percutaneous implants to partially implantable magnetic transcutaneous bone-conduction hearing implants using the Otomag® Sophono device in 12 pediatric patients, ranging in age from 5 to 12 years, with congenital unilateral CHL. Sound field thresholds, speech recognition threshold and speech comprehension at 65 dB were somewhat better in patients with the Baha implant (n=6) than the partially implantable hearing implant (n=6). Using a skull simulator, output was 10 to 15 dB lower with the partially implantable device than the Baha device.

Iseri et al (2015) described a retrospective, single-center study from Turkey comparing 21 patients treated with a transcutaneous, fully implantable Baha with 16 patients treated with a percutaneous device (the Baha Attract), Groups were generally similar at baseline, with most individuals undergoing Baha placement for chronic otitis media. Operating time was longer in patients treated with the transcutaneous partially implantable devices (46 minutes vs 26 minutes, p<0.05). Three patients treated with percutaneous devices had Holger grade 2 skin reactions, and 2 had stopped using their devices. Mean thresholds for frequencies 0.5 to 4.0 kHz were 64.4 dB without the Baha and 31.6 dB with the Baha in the percutaneous device group, and 58.3 dB without the Baha and 27.2 dB with the Baha in the transcutaneous device group. Frequency-specific threshold hearing gains did not differ significantly between groups. Mean hearing gain measured by speech reception threshold was statistically significantly smaller in the percutaneous group (24 dB vs 36.7 dB, p=0.02).

Gerdes et al (2016) published a retrospective single-center study comparing 10 patients with CHL implanted with the transcutaneous Bonebridge device to an audiologically matched control group of 10 patients with the percutaneous Baha BP100. There were similar significant improvements in aided thresholds, word recognition scores, and speech reception thresholds in noise for both devices. There were also no differences in subjective ratings for the APHAB scale. Mean functional gain was slightly higher (27.5 dB) for transcutaneous than for percutaneous (26.3 dB), but not significantly different.
**Observational Studies**

A moderately-sized body of observational studies – most of which are single center and with fewer than 10 patients has reported outcomes for transcutaneous, partially-implantable hearing systems. These studies are briefly described here to provide an overview of the functional gain and complications seen with the transcutaneously-coupled devices.

Dimitriadis et al (2016) reported a systematic review of observational studies of the BAHA Attract device including 10 studies (total N=89 patients; range, 1-27 patients). (60) Seventeen (19%) of the patients were children, of whom 5 had unilateral sensorineural hearing loss and 4 had CHL. Of the 27 (45%) adults, 22 had unilateral sensorineural hearing loss and 11 (18%) had bilateral mixed hearing loss. Audiologic and functional outcome measures and the timing of testing varied greatly in the studies. Summary measures were not reported. In general, audiologic and functional outcomes measured pre- and postimplantation showed improvement, although statistical comparisons were lacking in some studies.

Reddy-Kolamu et al (2016) reported on complications of the BAHA Attract (n=34) from a case series included all patients implanted in a single center between October 2013 and April 2015. (61) Patients ranged in age from 8 to 64 years, and follow-up ranged from 3 to 20 months. Twenty-three patients had no significant postoperative problems. Five patients required an alteration in magnet strength primarily due to implant site tenderness. One patient reported distressing tinnitus; 1 had the implant changed to an abutment system due to infection; and 1 had the magnet removed following trauma to the implant site. One patient has ongoing psoriasis problems. Two patients were converted to a newer, lighter sound processor.

In an early report on the device from 2011, Seigert reported on the use of a transcutaneous, partially implantable bone conduction hearing system (Otomag®). (62) Preliminary results of the partially implantable hearing system in 8 unilaterally and 4 bilaterally implanted patients showed average hearing gains of 31.2 ± 8.1 dB in free field pure tone audiogram. The free field suprathreshold speech perception at 65 dB increased from 12.9% preimplantation to 72.1% postimplantation.

Powell et al (2015) reported outcomes from a retrospective study, including 6 patients treated with the Otomag Sophono device and 6 treated with the BAHA Attract device. (63) Ten subjects were identified as the primary author’s patients and the remaining were identified through an Australian national hearing database. In the BAHA Attract group, mean air conduction thresholds across 4 frequencies (0.5, 1, 2, and 4 kHz) improved from 60.8 dB in the unaided state to 30.6 dB in the aided state. In the Sophono group, the mean 4-frequency AC thresholds improved from 57.8 dB in the unaided state to 29.8 dB in the aided state. Speech discrimination in noise scores did not differ significantly between devices.

O’Niel et al. (2014) reported outcomes for 10 pediatric patients with conductive hearing loss treated with the Otomag Sophono device at a single center. (64) A total of 14 ears were implanted with no surgical complications. The skin complication rate was 35.7%, including skin breakdown (n=2) and pain and erythema (n=5); negative outcomes resulted in 5 (36%) of 14 ears having significant enough difficulties to discontinue use for a period. The mean aided pure-tone average was 20.2 dB hearing level, with a mean functional gain of 39.9 dB hearing level. Patients without skin complications consistently used their devices, with an average daily use of 8 to 10 hours.

Centric et al. (2014) also reported outcomes for 5 pediatric patients treated with the Otomag Sophono device at a single center. (65) Etiologies of hearing loss were heterogeneous and included bilateral moderate or severe conductive hearing loss and unilateral sensorineural hearing loss. The average improvement in pure-tone average was 32 dB hearing level and the average improvement in speech response threshold was 28 dB hearing level. All patients were responding in the normal to mild hearing loss range in the operated ear after device activation. In a follow-up study from the same institution, Baker et al reported pooled outcomes for the first 11 patients treated with the Otomag Sophono and the first 6 patients treated with the Baha Attract. (60) Pre- and postimplant audiometric data were available for 11 years in the Sophono group and 5 in the Baha Attract group. Average improvement over all frequencies ranged from 24 to 43 decibel hearing level (dB HL) in the Sophono group and 32 to 45 dB HL in the Baha Attract group. Average improvement in PTA was 38 dB HL in the Sophono group and 41 dB HL in the Baha Attract group.

Other single-center observational series have described clinical experience with transcutaneous partially implantable BAHA devices. Marsella et al (2014) reported outcomes for 6 pediatric patients treated with the Otomag Sophono device for conductive or mixed hearing loss. (67) Median improvement in PTA was 33 dB HL
and median free-field PTA (0.5-3 kHz) with the device was 32.5 dB HL. Carr et (2015) reported outcomes for 10 patients treated with the BAHA Attract device, most commonly for chronic suppurative otitis media (n=3) and single-sided deafness (n=3). Patients did not show significant improvement in word discrimination score. Magliulo et al (2015) reported outcomes for 10 patients treated with the Otomag Sophono device after subtotal petrosectomy for recurrent chronic middle ear disease, a procedure that is associated with a conductive hearing loss of 50 to 60 dB. With the Sophono device postsurgery, there was an average acoustic improvement in AC of 29.7 dB, which was significantly better than the improvement seen with traditional AC hearing aids (18.2 dB).

In addition to studies of partially-implantable bone-conduction devices currently FDA-approved, a number of case series identified evaluated the Bonebridge implant, which is not currently cleared for marketing in the United States.(69-76)

**Section Summary**

Studies of transcutaneous, partially implantable BAHAs have typically used a retrospective within-subjects comparison of hearing thresholds with and without the device, although there have been 2 small (27 and 15 participants) prospective studies. There was heterogeneity in the audiologic and functional outcome measures used in the studies and the timing of testing. Studies of partially implantable BAHAs have generally demonstrated within-subjects improvements in hearing.

**Non-implanted BAHA with Softband**

In 2010, Christensen et al. reported on a retrospective five-year case review of ten children, with ages ranging from 6 months to 16 years of age, with bilateral conductive hearing loss due to congenital aural atresia (CAA) and/or microtia. The case-review study participants initially trialed the use of traditional bone-conduction hearing aids, then proceeded to the externally worn BAHA® with Softband™, and eventually to a unilateral implanted BAHA®. The devices were assessed for functional gain and hearing threshold measures at 500, 1000, 2000, and 4000 Hz frequencies. The findings of the report showed a statistically significant improvement when using the externally worn BAHA® with Softband™ over traditional bone-conduction hearing aids.(77)

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this policy are listed in the table below.

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<td>October 2013</td>
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<tr>
<td>NCT01822119a</td>
<td>Clinical Performance of a Transcutaneous Bone Conduction Hearing Solution (Baha® Attract System). A Multicentre, Open, Prospective Clinical Investigation. 3 Months Investigation With a 6 Months Follow-up</td>
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<td>February 2014</td>
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<td>NCT02092610a</td>
<td>Long Term Stability, Survival and Tolerability of a (Novel) Baha® Implant System</td>
<td>77</td>
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NCT: national clinical trial  
aDenotes industry-sponsored or cosponsored trial

**Summary of Evidence**

For individuals who have conductive or mixed hearing loss who receive an implantable bone-anchored hearing aid (BAHA) with a percutaneous abutment or a partially implantable BAHA with transcutaneous coupling to the
sound processor, the evidence includes observational studies that report pre-post differences in hearing parameters after treatment with BAHAs. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. No prospective trials were identified. Observational studies reporting on within-subjects changes in hearing have generally reported hearing improvements with the devices. Given the objectively measured outcomes and the largely invariable natural history of hearing loss in individuals who would be eligible for an implantable bone-conduction device, the demonstrated improvements in hearing after device placement can be attributed to the device. Studies of partially implantable BAHAs have similarly demonstrated within-subjects improvements in hearing. The single-arm studies have shown improvements in hearing in the device-aided state. No direct comparisons other than within-individual comparisons with external hearing aids were identified, but, for individuals unable to wear an external hearing aid, there may be few alternative treatments. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive a fully or partially implantable BAHA with contralateral routing of signal, the evidence includes 1 randomized controlled trial (RCT), multiple prospective and retrospective case series, and a systematic review. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. Single-arm case series, with sample sizes ranging from 9 to 180 patients, generally have reported improvements in patient-reported speech quality, speech perception in noise, and satisfaction with bone conduction devices with contralateral routing of signal. However, a well-conducted systematic review of studies comparing bone-anchored devices to hearing aids with contralateral routing of signal found no evidence of improvement in speech recognition or hearing localization. The single RCT included in the systematic review was a pilot study enrolling only 10 patients and, therefore, does not provide definitive evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

**American Academy of Otolaryngology-Head and Neck Surgery**

In 2016, The American Academy of Otolaryngology-Head and Neck Surgery updated it position statement on the use of implantable hearing devices. It states that the Academy 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. (78)

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

The Medicare Benefit Policy Manual provides detailed information about Medicare coverage, benefits and exclusions related to osseointegrated implants as prosthetic devices. (79,80)

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### References


Appendix

Figure 1. Implanted use of BAHA

Figure 2. Transcutaneous use of BAHA with Softband

Figure 1 source: http://emedicine.medscape.com/article/1604065-overview Accessed April 2017.

Figure 2 source: http://www.cochlear.com/wps/wcm/connect/uk/home/support/baha-system/connections/softband Accessed April 2017.

History

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<td>03/08/13</td>
<td>Replace policy. Updated with literature review and references renumbered. Policy statements unchanged.</td>
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<td>03/25/14</td>
<td>Replace policy. Added “magnetic” and “BAHA Attract” to last investigational policy statement. Clarified Benefit Application statement. Rationale updated with literature review through February 2014. Simplified Medicare National Coverage statement. References 3, 25, 34 added; others renumbered/removed. In appendix, revised figures 1-2, added source hyperlinks. Policy statement changed as noted. ICD-9 and ICD-10 codes removed from the policy; these are not utilized in adjudication and were informational only.</td>
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added. Policy statements unchanged. Added code L8695.

05/01/17 Annual review, changes approved April 11, 2017. Policy updated with literature review through December 20, 2016; references 23, 37, 53, 57, 59-61, and 69 added. Investigational statement for partially implantable devices is removed. Added unilateral or bilateral partially implantable bone conduction (bone-anchored) hearing aid(s) to medically necessary statement. Reasonable Useful Life (RUL) table moved to Policy Guidelines from Benefit Application section. In the Rationale section, deleted table of case series evaluating the BoneBridge implant as it is not currently cleared for marketing in the USA.

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پیام خبرگزاری‌های اطلاعاتی

پیام‌های خبرگزاری‌های اطلاعاتی

به عنوان خبرگزاری‌های اطلاعاتی، ما به شما اطلاع می‌دهیم که در تاریخ ۸ سپتامبر ۲۰۱۷، این اطلاعات در دفتر خبرگزاری‌های اطلاعاتی و مجلات بین‌المللی در این مورد و اطلاعاتی که از طریق بهره‌برداری از این اطلاعات در مورد تاریخ‌های متداول و مهم در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعات در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاعاتی در این اکثریت اطلاعاتی در تصمیم‌گیری و محاسبه‌های کلیدی این اطلاу...