Implantable Bone-Conduction and Bone-Anchored Hearing Aids

Policy # 00004
Original Effective Date: 06/24/2002
Current Effective Date: 10/16/2013

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider the use of unilateral or bilateral implantable bone-conduction (bone-anchored) hearing aid(s) as an alternative to air-conduction hearing aid in patients with a conductive or mixed hearing loss to be eligible for coverage.

Patient Selection Criteria
Coverage eligibility for the use of unilateral or bilateral implantable bone-conduction (bone-anchored) hearing aids as an alternative to an air-conduction hearing aid in patients 5 years of age and older with a conductive or mixed hearing loss will be considered when at least 1 of the following criteria are 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 ear canal and/or tympanic cavity; OR
- Dermatitis of the external canal; AND

Meet the following audiologic criteria:

- 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).
- For bilateral implantation, patients should meet the above audiologic criteria, and have a symmetrically conductive or mixed hearing loss as defined by 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, or less than 15 dB at individual frequencies.

When Services Are Eligible for Coverage
Based on review of available data, the Company may consider an implantable bone-conduction (bone-anchored) hearing aid as an alternative to an air-conduction contralateral routing of signal hearing aid in patients five 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 to be eligible for coverage.
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When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers other uses of bone-conduction (bone-anchored) hearing aids, including use in patients with bilateral sensorineural hearing loss, to be investigational.*

Based on review of available data, the Company considers partially implantable bone conduction hearing systems using magnetic coupling for acoustic transmission (e.g., Otomag Alpha 1 [M]) to be investigational.*

Based on review of available data, the Company considers implantable bone conduction hearing aids when patient selection criteria are not met to be investigational.*

Background/Overview

Conventional external hearing aids can be generally subdivided into air-conduction hearing aids and bone-conduction hearing aids. Air-conduction hearing aids require the use of ear molds, which may be problematic in patients with chronic middle ear and ear canal infections, atresia of the external canal, or an ear canal that cannot accommodate an ear mold. An implantable, bone-anchored hearing aid (BAHA®‡) has been investigated as an alternative to conventional bone-conduction hearing aids.

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. 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 (greater or equal to 80 dB). 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 signals (CROS) is a system in which a microphone on the affected side transmits a signal to an air-conduction hearing aid on the normal or less affected side.

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.

The BAHA implant system works by combining a vibrational transducer coupled directly to the skull via a small titanium implant anchored in the temporal bone. The system is based on the process of osseointegration through which living tissue integrates with titanium in the implant over a period of 3 to 6 months, allowing amplified and processed sound to be conducted 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.
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A partially implantable bone conduction hearing system, the Otomag Alpha 1(M), is available as an alternative to the BAHA systems. With this technique, acoustic transmission occurs via magnetic coupling of the externally and internally implanted device components. The Otomag Alpha 1(M) bone conduction hearing vibrator contains twin magnets that adhere externally to titanium-encased twin magnets implanted in shallow bone beds. Since the processor adheres magnetically to the implant, there is no need for a percutaneous abutment. 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
There are four BAHA sound processors for use with the BAHA auditory osseointegrated implant system manufactured by Cochlear Americas (Englewood, CO) that have received 510(k) clearance from the FDA:

- BAHA® Cordelle II™
- BAHA® Divino™
- BAHA® Intenso™ (digital signal processing)
- BAHA® BP100™

The FDA approved the BAHA system 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 one 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.

The BAHA implant is cleared for use in children aged five years and older, and in adults.

Bone-anchored hearing aid sound processors can also be used with the BAHA® Softband™. With this application there is no implantation surgery. The sound processor is attached to the head using either a hard or soft headband. The amplified sound is transmitted transcutaneously to the bones of the skull for transmission to the cochlea. The BAHA Softband received FDA clearance in 2002 for use in children under the age of five. As this application has no implanted components, it is not addressed in the policy.

In November 2008, the device “OBC Bone Anchored Hearing Aid System” (Oticon Medical, Kongebakken, Denmark) was cleared by the FDA for marketing through the 510(k) process. Subsequently, additional bone conduction hearing systems have received 510(k) marketing clearance from the FDA including Otomag (Sophono, Inc., Boulder, CO) and Ponto (Oticon Medical). The Ponto Pro processor can be used with the Oticon or BAHA implants. In May 2011, Sophono, Inc. and Oticon Medical partnered to receive 510(k) marketing clearance from the FDA for the Otomag Alpha 1(M), a partially implantable bone conduction hearing system. All of these devices were determined to be substantially equivalent to existing devices (e.g., the Xomed Audiant, which was FDA cleared for marketing in 1986 but is no longer available). They share similar indications as the Cochlear Americas BAHA devices.
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Centers for Medicare and Medicaid Services (CMS)
No national coverage determination. The Medicare Benefit Policy Manual references hearing aids and auditory implants, stating that hearing aids are excluded from coverage, including air-conduction and bone-conduction devices. However, devices which produce the perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized. Along with cochlear and auditory brainstem implants, the benefit manual specifically refers to osseointegrated implants as prosthetic devices.

Rationale/Source
The most recent literature search was performed for the period December 2011 to December 7, 2012. No randomized controlled trials (RCTs) have compared implantable bone-conduction hearing aids to other hearing augmentation devices, or sham devices. The literature is characterized by observational studies that report pre- and post-hearing outcomes in patients treated with BAHA. Many of these studies combine patients with differing underlying disease states and indications. Following is a summary of key findings.

Mixed etiologies of hearing loss
Systematic Reviews
A systematic review by the Health Technology Assessment Program was published in 2011 on the use of BAHAs for bilateral hearing impairment. The authors noted that the quality of available studies on the use of BAHAs is weak. No studies with control groups were identified for the review. Cohort pre-post studies and cross-sectional comparative studies demonstrate improvements in hearing with use of BAHAs over conventional bone-conduction hearing aids or unaided hearing. However, whether improvements in hearing with BAHAs are greater than air-conduction hearing aids is uncertain. Additionally, bilateral use of BAHAs improved hearing outcomes in some patients over unilateral use, but the evidence was uncertain. Implant loss was noted to be between 6.1% and 19.4%. The authors noted hearing-specific quality of life improved, but overall quality of life did not differ.

Observational Studies
In 2010, 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.
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In 2004, McLarnon and colleagues reported outcomes (benefits) for BAHAs by patient subgroups based on 69 of 94 (73%) patients who completed a questionnaire. This study noted the greatest benefit in those with congenital ear disorders. It also showed benefit to restoring stereo hearing to patients with an acquired unilateral hearing loss after acoustic neuroma surgery.

In 2008, Tringali and colleagues surveyed patients using a BAHA to compare patient satisfaction by indication: 52 respondents with conductive or mixed hearing loss (44 with chronic otitis and 8 with malformation of the middle ear) compared with 118 with single-sided deafness (SSD) (2 after surgery for meningioma, idiopathic sudden deafness, sensorineural hearing loss complicating surgery of the middle ear). Levels of satisfaction and quality of life were significantly poorer in the SSD than in the conductive hearing loss (CHL) group, although generally good with the exception of sound localization.

Moderate to Severe Conductive or Mixed Hearing Loss
Reported studies have suggested that the BAHA is associated with improved hearing outcomes compared to external bone-conduction hearing aids and equivalent outcomes compared to a conventional air-conduction hearing aid.

Bilateral Devices in Conductive or Mixed Hearing Loss
Use of bilateral devices has been evaluated in patients with conductive or mixed hearing losses. 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.

Janssen and colleagues (2012) conducted a systematic review to assess the outcomes of bilateral versus unilateral BAHA for individuals with bilateral permanent CHL. 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. 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 and others reported on findings from 25 patients who were using bilateral devices. They found that both speech recognition in noise and
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directional hearing improved with the second device. In a 2004 publication, Priwin and colleagues reported similar findings in 12 patients with bilateral devices. A consensus statement published in 2005 concluded that bilateral devices resulted in binaural hearing with improved directional hearing and improved speech-in-noise scores in those with bilateral conductive hearing loss and symmetric bone-conduction thresholds. A number of additional studies that are cited in this report found benefits similar to those noted in the studies of the Bosman et al. and Priwin et al. reports. Positive outcomes continue to be reported: Dun and colleagues identified improvements in the Glasgow Benefit Inventory in children (n=23), while Ho and colleagues report the same benefit in adults (n=93). Thus, based on these numerous studies, bilateral devices may be considered medically necessary when there is bilateral conductive or mixed hearing loss with symmetric bone-conduction thresholds.

Unilateral Sensorineural Hearing Loss
Several centers have reported on findings from observational studies designed to evaluate the benefits of BAHA for patients with unilateral sensorineural hearing loss (single-sided deafness). Most of these studies have been retrospective. In one prospective study conducted within a hospital auditory implant center in the United Kingdom, Pai and colleagues reported significant improvement in the average score in all three sections (speech hearing, spatial hearing, other qualities) of the spatial and qualities of hearing scale SSQ questionnaire following a BAHA implant in 25 adult patients.

Zeitler and colleagues reported on a retrospective case series of 180 patients undergoing unilateral or bilateral BAHA for single-sided deafness with residual hearing in the implanted ear within a university medical center in the U.S. Significant improvement was reported in objective hearing measures (speech-in-noise and monosyllabic word tests) following BAHA implantation. Subjective benefits from BAHA varied across patients according to results from the Glasgow Hearing Aid Benefit Profile, but patients with residual hearing in the affected ear tended toward improved satisfaction with their device postoperatively. Nicolas and colleagues undertook a retrospective review of 36 patients implanted with a BAHA within a university medical center in France. Their results showed an improvement in speech perception in noise with the BAHA, but no improvement in sound localization based on a 2-year follow-up period.

Baguley and colleagues reviewed the evidence for contralateral BAHAs in adults with acquired unilateral sensorineural hearing loss. None of the 4 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 CROS systems. The authors of this review did note shortfalls in the studies reviewed.

Lin and colleagues reported on use of the BAHAs in 23 patients with unilateral deafness and noted that speech recognition in noise was significantly better with the BAHA device than with the air-conduction CROS device. While the report also comments that benefit was seen in those with moderate sensorineural hearing loss in the contralateral ear (25–50 dB), this conclusion was based on 5 patients. Larger studies are needed before changes can be considered in the policy statement regarding use in this clinical situation.
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Two studies of BAHAs for congenital unilateral conductive hearing impairment are reported by Kunst and colleagues. In one study, aided and unaided hearing was assessed in 20 patients using sound localization and speech recognition-in-noise tests. Many patients showed unexpectedly good unaided performance; however, non-significant improvements were observed in favor of the BAHA. Six of 18 patients with a complete data set showed no improvement at all; however, compliance with BAHA use in this patient group was remarkably high, suggesting patient benefit. The same authors evaluated 10 adults and 10 children using 2 disability-specific questionnaires and found an overall preference for the BAHA over unaided hearing in several specific hearing situations. Improvement on the Glasgow Children’s Benefit Inventory was most prominent in the learning domain. The 10 adults showed an already good score on the Speech, Spatial, and Qualities of hearing scale in the unaided situation.

In 2010, Gluth and colleagues reported on 21 patients with profound unilateral sensorineural hearing loss followed for an average of 3.2 years after BAHA implantation. Perceived benefits and satisfaction were reported to improve significantly in BAHA users, and 81% continued using the device long term. However, severe local skin reactions were frequently experienced (38% Grade 2 and above).

Children Younger Than Age 5 Years
A 2008 review article notes that for children younger than age 5 years, other solutions (such as a bone conductor with transcutaneous coupling) should be utilized. This recommendation is in agreement with the FDA clearance of the osseointegration implant only for children 5 years of age and older, and adults. This is reflected in the policy statements.

The BAHA device has been investigated in children younger than 5 years in Europe and the United Kingdom. A number of reports describe experience with preschool children or children with developmental issues that might interfere with maintenance of the device 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 to 6 months, a second procedure is performed to connect the abutment through the skin to the fixture.

Marsella and colleagues have reported on their center’s experience in Italy with pediatric BAHA from the inception of their program in 1995 to December 2009. A total of 47 children (21 females and 26 males) were implanted; 7 of these were younger than 5 years. The functional gain was significantly better with BAHA than conventional bone-conduction hearing aids, and there was no significant difference in terms of functional outcome between the 7 patients receiving a BAHA at an age younger than 5 years and 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 conclusions are limited by the small number of children less than 5 years of age in the study and the limited power to detect a difference between younger and older children.

Davids and colleagues at the University of Toronto 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 younger than 5 years and a control group of 20 older children. Children with cortical bone thickness greater than 4 mm underwent a single-stage procedure. The interstage interval for
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children having 2-stage procedures was significantly longer in the study group 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 the time of writing. McDermott et al. reported on the role of BAHAs 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. All patients were using their BAHA devices after a 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.

Adverse Events
In 2012, Dun and colleagues 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 the University Medical Center in the Netherlands. The study investigators also examined device usage and comparisons between different patient age groups (children, adults, and elderly patients) over a 5-year follow-up period. Implant loss was 8.3%. 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 compared with adults and elderly patients (p<0.05). Implant survival was lower in patients with mental retardation compared with patients without mental retardation (p=0.001).

In 2010, Hobson and colleagues 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. 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%). The 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, BAHAs were still 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%); removal of the implant or revision surgery was required in 10 patients (37%); 24 patients (89%) experienced soft tissue overgrowth and infection; and 7 patients experienced implant trauma. Chronic infection and overgrowth at the abutment prevented use of the implant in 3 patients (11%).

Partially Implantable Bone Conduction Hearing Aids
In 2011, Seigert reported on the use of a partially implantable bone conduction hearing system that uses magnetic coupling for acoustic transmission. This hearing system is reported to have been implanted in more than 100 patients followed in the past 5 years, but results are only presented on 12 patients. Since the acoustics must pass through the skin rather than by direct bone stimulation through an abutment on the BAHA-type implants, Seigert reports sound attenuation is reduced by less than 10 dB. The preliminary
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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.

Ongoing Clinical Trials
A search of online site ClinicalTrials.gov in December 7, 2012 found 2 ongoing studies. The first study is a small randomized trial being undertaken in a Canadian tertiary university center comparing the effect of BAHA and a CROS hearing aid on speech perception scores when listening to speech in quiet and in noise. (NCT01715948) This trial will also investigate patients’ reported benefits with each device during everyday situations. In order to compare the BAHA and CROS, users of BAHA will be given a 2-week trial period with the ‘Unitron Tandem’ CROS hearing aid. Participants will be randomly assigned to wear either their BAHA for 2 weeks or the trial CROS for 2 weeks. Expected enrollment for this study is 10 patients, with an estimated trial completion date of December 2013.

The second study is a Phase IV open study evaluating the effectiveness of bone-anchored hearing aids for conductive or mixed hearing loss, or unilateral deafness. (NCT01264510) The status of this latter study is ongoing, but not recruiting participants. Expected enrollment for this study is 150 patients, with an estimated initial completion date of August 2011.

Summary
Bone-conduction hearing aids function by transmitting sound waves through the bone to the ossicles of the middle ear. The available evidence for unilateral or bilateral implantable bone-conduction (bone-anchored) hearing aid(s) consists of observational studies that report pre- post- differences in hearing parameters after treatment with BAHA. While this evidence is not ideal, it is sufficient to demonstrate improved net health outcome for patients 5 years of age or older in certain situations. The evidence supports the use of these devices in patients with conductive or mixed hearing loss who meet other medical and audiologic criteria. For patients with single-sided sensorineural deafness, a binaural hearing benefit may be provided by way of contralateral routing of signals to the hearing ear. There is evidence that bilateral devices improve hearing to a greater degree than do unilateral devices. Bone-anchored hearing aids may be considered as an alternative to air-conduction devices in these patients and therefore, these devices may be considered medically necessary in these situations. Given the lack of both high-quality evidence and FDA approval, other uses of bone-conduction (bone-anchored) hearing aids, including use in children younger than 5 years and patients with bilateral sensorineural hearing loss, is considered investigational.

The available evidence for partially implantable bone-conduction hearing systems is preliminary and very limited. Therefore, conclusions on net health outcomes cannot be made, and partially implantable bone-conduction hearing systems are considered investigational.

References
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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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Policy History

Original Effective Date:  06/24/2002
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06/11/2002  Medical Director review
06/20/2002  Medical Policy Committee review
06/24/2002  Managed Care Advisory Council approval. Format revision. No substance change to policy.
07/06/2004  Medical Director review
07/20/2004  Medical Policy Committee review. Format revision, Rationale/Source added to policy. No substance change to policy.
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<td>08/09/2006</td>
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<td>10/10/2007</td>
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<td>10/17/2007</td>
<td>Medical Policy Committee approval. Policy statements updated and clarified related to eligibility for coverage for unilateral and bilateral sensorineural hearing loss. Policy statement added concerning investigational uses, including bilateral sensorineural hearing loss. Policy title changed to add “and Bone-Anchored”.</td>
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<td></td>
<td>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). For bilateral implantation, patients should meet the above audiologic criteria, and have a symmetrically conductive or mixed hearing loss as defined by 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, or less than 15 dB at individual frequencies.</td>
</tr>
<tr>
<td>10/11/2012</td>
<td>Medical Policy Committee review</td>
</tr>
<tr>
<td>10/31/2012</td>
<td>Medical Policy Implementation Committee approval. Added investigational statement for partially implantable hearing systems.</td>
</tr>
<tr>
<td>02/04/2013</td>
<td>Coding updated</td>
</tr>
<tr>
<td>10/03/2013</td>
<td>Medical Policy Committee review</td>
</tr>
<tr>
<td>10/16/2013</td>
<td>Medical Policy Implementation Committee approval. No change to coverage.</td>
</tr>
</tbody>
</table>

Next Scheduled Review Date: 10/2014

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
Implantable Bone-Conduction and Bone-Anchored Hearing Aids

Policy # 00004
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Current Effective Date: 10/16/2013

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
   A. In accordance with nationally accepted standards of medical practice;
   B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
   C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.