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Medical Policy Manual

Topic: Implantable Bone Conduction and Bone-Anchored Hearing Aids

Date of Origin: July 2003

Section: Surgery

Approved Date: April 2014

Policy No: 121

Effective Date: July 1, 2014

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION[1]

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. In these patients, bone-conduction hearing aids may be an alternative.

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. Semi-implantable bone-conduction hearing aids have been investigated as an alternative.

The bone-anchored hearing aid (BAHA) implant systems, also called osseointegrated devices, work by combining 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 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.

Partially implantable magnetic bone conduction hearing systems are available as an alternative to bone conduction hearing systems connected percutaneously via an abutment. With this technique, acoustic transmission occurs transcutaneously via magnetic coupling of the external sound processor and the internally implanted device components. The bone conduction hearing processor contains a magnet that adheres 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 facilitate greater transmission of acoustics between magnets, skin thickness may be reduced to 4-5 mm over the implant when it is surgically placed.

Regulatory Status

The following *Baha® sound processors, marketed by Cochlear™ Americas (also called Cochlear™), have received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for use with the Baha auditory osseointegrated implant (hearing aid) systems (such as the Baha® system):

- Baha ® Cordelle II
- Baha® ca (Cochlear™)
- Baha Divino®
- Baha® Intenso™ for digital signal processing
- Baha® BP100™
- Baha® 4 Sound Processor (upgraded from the Baha® BP100™)

*Note: These devices may be referred to as Cochlear™ Baha® systems or Cochlear osseointegrated implants, reflecting the manufacturer's name. These devices are bone conduction hearing aids and *should not* be confused with cochlear implants which are prostheses that replace a damaged cochlea in the inner ear. Cochlear implants are addressed separately in Medical Policy, Surgery No. 8 (see Cross References).

The FDA approved the Cochlear® Americas Baha system (initially approved under the trade name Branemark Bone-Anchored Hearing Aid [BAHA™] by Entific Medical Systems, Inc.) 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 5 years and older, and in adults.

Subsequent bone conduction hearing systems (listed below) share similar indications as the Cochlear Americas BAHA devices:

- OBC Bone Anchored Hearing Aid System" (Oticon Medical)
- Otomag® (Sophono, Inc.)
- Ponto (Oticon Medical).
- Ponto Pro processor (Oticon Medical), to be used with the Oticon or BAHA implants.

The following two partially implantable magnetic bone conduction devices have received FDA 510(k) clearance:

- Otomag Alpha 1(M) (Sophono, Inc. and Oticon Medical), a partially implantable bone conduction hearing system.
- Baha® Attract (Cochlear®)

Baha 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 5 years. As this application has no implanted components, it is not addressed in the policy.

MEDICAL POLICY CRITERIA

Notes:

- This policy applies *only* to bone anchored hearing aid systems, also called osseointegrated implants. It does *not* apply to cochlear implants which are addressed separately in Medical Policy, Surgery No. 8 (see Cross References).
- Bone anchored hearing aids (BAHAs) are bone conduction hearing aids. There may be specific member benefit language addressing coverage of hearing aids. Any specific contract language supersedes medical policy. Unless otherwise specified, the contract language addressing coverage of hearing aids applies to both surgically implanted bone conduction hearing aids and externally worn air conduction hearing aids.

I. Unilateral or 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 with a conductive or mixed hearing loss when both of the following criteria (A and B) are met:

A. At least one of the following criteria is met:

1. Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear;

2. Chronic external otitis or otitis media;

3. Tumors of the external canal and/or tympanic cavity;

4. Dermatitis of the external canal.

B. One of the following audiologic criteria is met:

1. A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3

kHz of dB lower than or equal to 45 dB (OBC and BP100 devices), 55 dB (Intenso device), or 65 dB (Cordele II device) in patients with unilateral hearing loss (see Policy Guidelines below); or

2. For bilateral implantation, patients should have a symmetrically conductive or mixed hearing loss (measured without augmentation) 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 (4 kHz for OBC, Ponto Pro and Otomag Alpha 1 [M]), or less than 15 dB at individual frequencies.

II. An implantable bone-conduction (bone-anchored) hearing aid may be considered **medically necessary** as an alternative to an air-conduction contralateral routing of signals hearing aid in patients 5 years of age and older with single-sided sensorineural deafness and normal hearing in the other ear.

III. Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in patients with bilateral sensorineural hearing loss, are considered **investigational**.

IV. Partially implantable magnetic bone conduction hearing systems using magnetic coupling for acoustic transmission are considered **investigational**.

POLICY GUIDELINES

Pure tone hearing tests measure the faintest level (hearing threshold) at which a tone can be heard at selected frequencies approximately 50% of the time. Each ear is tested separately. The pure tone average threshold hearing level is calculated separately for each ear by averaging the hearing levels at each frequency. For example, if a patient's bone-conduction hearing threshold in the right ear at frequencies 0.5, 1, 2, and 3 kHz is 20, 20, 30, and 40 dB, respectively, the pure tone average for that ear is (20 + 20 + 30 + 40) ÷ 4 = 27.5 dB.

SCIENTIFIC EVIDENCE[1]

Hearing results of semi-implantable bone-conduction hearing aids may be compared either to 1) external bone-conduction hearing aids in patients with atresias who are unable to use external air-conduction hearing aids, or 2) external air-conduction hearing aids in patients who are unable to tolerate air-conduction hearing aids due to chronic infection. Reported studies have suggested that the bone-anchored hearing aid (BAHA) is associated with improved hearing outcomes compared to external bone-conduction hearing aids and equivalent outcomes compared to conventional air-conduction hearing aids.[2-5]

Unilateral Devices

Systematic Review

Baguley and colleagues reviewed the evidence for contralateral BAHAs in adults with acquired unilateral sensorineural hearing loss.[6] 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

signals (CROS) systems. The authors of this review did note the following shortfalls in the studies reviewed:

- The BAHA was always trialed after the CROS aid;
- CROS aids were only trialed for 4 weeks;
- No studies used any measure of hearing handicap when selecting subjects;
- Two studies had a patient selection bias
- All studies were underpowered
- Double reporting of patients occurred

Randomized Controlled Trials (RCTs)

No RCTs of unilateral BAHAs have been published.

Nonrandomized Studies

Since the systematic review was published, 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. The following summaries are examples of observational and comparative trials with at least 100 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.[7] 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.
- 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.[8] 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 concluded that this population benefited from bone-anchored and Softband-held conductive hearing aids based on mean scores. However, the study is limited due to the retrospective study design, heterogeneous patient population, a lack of pre-intervention measures, or a controlled comparator group.

Bilateral Devices

Use of bilateral devices has been evaluated in nonrandomized studies of 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.

Systematic Reviews

- A systematic review by the Health Technology Assessment Program was published in 2011 on the use of bone-anchored hearing aids (BAHAs) for bilateral hearing impairment.[9,10] 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 demonstrated 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.
- In 2012 Janssen and colleagues reported similar findings in a systematic review that assessed the outcomes of bilateral versus unilateral BAHA for individuals with bilateral permanent conductive hearing loss (CHL).[11] 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 three 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.

Randomized Controlled Trials (RCTs)

No RCTs of bilateral BAHAs have been published.

Nonrandomized Studies

No new studies have been published since the most recent systematic review.

Adverse Effects of BAHAs

Meta-Analysis

In 2103 Kiringoda et al. reported on a meta-analysis of complications related to BAHA implants. Included in the meta-analysis were 20 studies that evaluated complication in 2134 adult and pediatric patients who received a total of 2310 BAHA implants.[12] The quality of available studies was considered poor and lacking in uniformity. Most complications related to BAHA implants were minor skin reactions. Holgers Grade 2 to 4 skin reactions were reported to occur from 2.4% to 38.1% in all studies. Zero to 18% of implants failed osseointegration in adult and mixed population studies while 0%

to 14.3% failed osseointegration in pediatric population studies. Adult and mixed population studies reported revision surgery was required in 1.7% to 34.5% of cases while pediatric population studies reported required revision surgery in 0.0% to 44.4% of cases. Implant loss occurred in 1.6% to 17.4% in adult and mixed population studies and from 0.0% to 25% in pediatric studies.

Clinical Trials

No new studies have been published since the meta-analysis summarized above.

Partially Implantable Bone Conduction Hearing Aids

- In 2011, Seigert reported on the use of a partially implantable bone conduction hearing system (Otomag) that uses magnetic coupling for transcutaneous acoustic transmission.[13] This hearing system was reported to have been implanted in more than 100 patients followed in the past 5 years, but results were only presented on 12 patients. Since the acoustics must pass through the skin rather than by direct bone stimulation through a percutaneous abutment on the BAHA-type implants, Seigert reported sound attenuation was reduced by less than 10 dB. The 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. Nevertheless conclusions based upon this study are limited by the small sample size, lack of treatment randomization or appropriate comparison groups.
- 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.[14] 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.

Children Under Age 5 Years

The BAHA device has been used successfully in children younger than 5 years in Europe and the United Kingdom. (The most recent [1999] update of the U.S. Food and Drug Administration [FDA] notification lists age less than 5 years as a contraindication.) 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 two-stage procedure is used in young children with the fixture placed into the bone at the first stage and, after 3 to 6 months to allow for osseointegration, a second procedure to connect the abutment through the skin to the fixture.

The literature on the use of these devices in children consists of a review article and several nonrandomized studies.

- 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.[15] This recommendation is in agreement with the FDA clearance of the osseointegration implant only for children 5 years of age and older, and adults.
- Davids and colleagues at the University of Toronto provided BAHA devices to children less 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.[16] 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 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 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.[17] All patients were using their BAHA devices after a follow-up of 14 months. No fixtures were lost, and skin problems were encountered in 3 patients. All 15 patients had improved social and physical functioning as a result of better hearing.

Position Statements

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)[18]

The updated position statement specifies that implantation of percutaneous, transcutaneous, or semi-implantable or totally implantable bone conduction hearing devices are acceptable for relief of hearing impairment when performed by or in collaboration with a qualified otolaryngologist-head and neck surgeon. No specific patient selection criteria are provided, stating only that device use "must adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the Food and Drug Administration in the United States."

Summary

The available evidence is sufficient to demonstrate improved net health outcomes for unilateral or bilateral implantable bone-conduction (bone-anchored) hearing aid(s) as an alternative to air-conduction hearing aids in select patients aged 5 years and older. In addition, a binaural hearing benefit may be provided for patients with single-sided sensorineural deafness by the routing of signals to the hearing ear. Therefore, use of these devices is considered medically necessary for patients who meet the policy criteria. These devices are considered investigational for patients who do not meet the policy criteria, including but not limited to children younger than 5 years and patients with bilateral sensorineural hearing loss.

The available evidence for partially implantable magnetic 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

1. BlueCross BlueShield Association Medical Policy Reference Manual "Implantable Bone-Conduction and Bone-Anchored Hearing Aids." Policy No. 7.01.03
2. Snik, AF, Mylanus, EA, Cremers, CW. The bone-anchored hearing aid compared with conventional hearing aids. Audiologic results and the patients' opinions. *Otolaryngol Clin North Am*. 1995 Feb;28(1):73-83. PMID: 7739870
3. Wazen, JJ, Caruso, M, Tjellstrom, A. Long-term results with the titanium bone-anchored hearing aid: the U.S. experience. *Am J Otol*. 1998 Nov;19(6):737-41. PMID: 9831146

4. van der Pouw, CT, Snik, AF, Cremers, CW. The BAHA HC200/300 in comparison with conventional bone conduction hearing aids. *Clin Otolaryngol Allied Sci*. 1999 Jun;24(3):171-6. PMID: 10384840
5. Granstrom, G, Tjellstrom, A. The bone-anchored hearing aid (BAHA) in children with auricular malformations. *Ear Nose Throat J*. 1997 Apr;76(4):238-40, 42, 44-7. PMID: 9127523
6. Baguley, DM, Bird, J, Humphriss, RL, Prevost, AT. The evidence base for the application of contralateral bone anchored hearing aids in acquired unilateral sensorineural hearing loss in adults. *Clin Otolaryngol*. 2006 Feb;31(1):6-14. PMID: 16441794
7. Zeitler, DM, Snapp, HA, Telischi, FF, Angeli, SI. Bone-anchored implantation for single-sided deafness in patients with less than profound hearing loss. *Otolaryngol Head Neck Surg*. 2012 Jul;147(1):105-11. PMID: 22368043
8. Ramakrishnan, Y, Marley, S, Leese, D, Davison, T, Johnson, IJ. Bone-anchored hearing aids in children and young adults: the Freeman Hospital experience. *J Laryngol Otol*. 2011 Feb;125(2):153-7. PMID: 20849670
9. Colquitt, JL, Loveman, E, Baguley, DM, et al. Bone-anchored hearing aids for people with bilateral hearing impairment: a systematic review. *Clin Otolaryngol*. 2011 Oct;36(5):419-41. PMID: 21816006
10. Colquitt, JL, Jones, J, Harris, P, et al. Bone-anchored hearing aids (BAHAs) for people who are bilaterally deaf: a systematic review and economic evaluation. *Health Technol Assess*. 2011 Jul;15(26):1-200, iii-iv. PMID: 21729632
11. Janssen, RM, Hong, P, Chadha, NK. Bilateral bone-anchored hearing aids for bilateral permanent conductive hearing loss: a systematic review. *Otolaryngol Head Neck Surg*. 2012 Sep;147(3):412-22. PMID: 22714424
12. Kiringoda, R, Lustig, LR. A meta-analysis of the complications associated with osseointegrated hearing aids. *Otol Neurotol*. 2013 Jul;34(5):790-4. PMID: 23739555
13. Siegert, R. Partially implantable bone conduction hearing aids without a percutaneous abutment (Otomag): technique and preliminary clinical results. *Adv Otorhinolaryngol*. 2011;71:41-6. PMID: 21389703
14. Hol, MK, Nelissen, RC, Agterberg, MJ, Cremers, CW, Snik, AF. Comparison between a new implantable transcutaneous bone conductor and percutaneous bone-conduction hearing implant. *Otol Neurotol*. 2013 Aug;34(6):1071-5. PMID: 23598702
15. Snik, A, Leijendeckers, J, Hol, M, Mylanus, E, Cremers, C. The bone-anchored hearing aid for children: recent developments. *Int J Audiol*. 2008 Sep;47(9):554-9. PMID: 18821224
16. Davids, T, Gordon, KA, Clutton, D, Papsin, BC. Bone-anchored hearing aids in infants and children younger than 5 years. *Arch Otolaryngol Head Neck Surg*. 2007 Jan;133(1):51-5. PMID: 17224524
17. McDermott, AL, Williams, J, Kuo, MJ, Reid, AP, Proops, DW. The role of bone anchored hearing aids in children with Down syndrome. *Int J Pediatr Otorhinolaryngol*. 2008 Jun;72(6):751-7. PMID: 18433885
18. American Academy of Otolaryngology Head and Neck Surgery. Implantable Hearing Devices. 2013. [cited 03/17/2014]; Available from: http://www.entnet.org/Practice/policyImplantableHearingDevices.cfm

CROSS REFERENCES

Cochlear Implant, Surgery Policy No. 8

CODES	NUMBER	DESCRIPTION
The following CPT codes describe semi-implantable bone conduction hearing aids:		
CPT	69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone*
*The Audiant™ bone conductor is a type of electromagnetic bone conduction hearing device. While this product is no longer actively marketed, patients with existing Audiant devices may require replacement, removal, or repair.		
	69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy**
	69715	; with mastoidectomy**
	69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
	69718	; with mastoidectomy
**These codes describe implantation of the Baha®, Pronto™, and similar devices.		
HCPCS	L8690	Auditory osseointegrated device, includes all internal and external components***
	L8691	Auditory osseointegrated device, external sound processor, replacement
	L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
***These codes describe the Baha®, Pronto™, and similar devices.		