Medical Coverage Policy | Implantable Bone Conduction and Bone Anchored Hearing Aids

EFFECTIVE DATE: 12|01|2019
POLICY LAST UPDATED: 10|01|2019

OVERVIEW

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 patients with unilateral single-sided sensorineural hearing loss.

This policy is applicable to Commercial Products only.
For BlueCHiP for Medicare, the service identified in this policy is not considered part of a hearing aid benefit, as this policy is specific to an implantable hearing device.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Commercial Products

Unilateral or bilateral fully or partially 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 with the following indications:

- Congenital or surgically induced malformations (eg, 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

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

Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in patients with bilateral sensorineural hearing loss, are considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

In situations where the insertion of the device is not medically necessary, re-insertion of the device after removal is also considered not medically necessary.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable surgery benefits/coverage and limitations of benefits/coverage when services are not medically necessary.

BACKGROUND

HEARING LOSS

Hearing loss is described as conductive, sensorineural, or mixed and can be unilateral or bilateral. Normal hearing detects sound at or below 20 dB (decibel). The American Speech-Language-Hearing Association has defined the degree of hearing loss based on pure-tone average (PTA) detection thresholds as mild (20-40 dB), moderate (40-60 dB), severe (60-80 dB), and profound (≥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 to 8 kHz.

Sound amplification using an 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.

Treatment

External bone-conduction hearing devices function by transmitting sound waves through the bone to the ossicles of the middle ear. The external devices must be applied close to the temporal bone, with either a steel spring over the top of the head or 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 the process of osseointegration through which living tissue integrates with titanium in the implant over a period of 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.

Partially implantable magnetic bone-conduction hearing systems, also referred to as transcutaneous bone-anchored systems, are an alternative to bone-conduction hearing systems that connect to bone 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 magnets that adhere externally to magnets implanted in shallow bone beds with the bone-conduction hearing implant. Because 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 may be reduced to 4 to 5 mm over the implant when it is surgically placed.

Several implantable bone-conduction hearing systems have been approved by the US Food and Drug Administration for marketing through the 510(k) process:

- Baha® Auditory Osseointegrated Implant System, manufactured by Cochlear Americas
  - Baha® 5
  - Baha® Cordelle II
  - Baha Divino®
  - Baha Intenso® (digital signal processing)

    - Baha® BP100
    - Baha® 4 (upgraded from the BP100)
  - OBC Bone-Anchored Hearing Aid System, manufactured by Oticon Medical
  - Ponto Bone-Anchored Hearing System, manufactured by Oticon Medical

The FDA cleared these systems for use in children ages 5 years and older and 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 (ie, single-sided deafness);
- Patients who are candidates for an AC CROS hearing aid but who cannot or will not wear an AC CROS device

The FDA also cleared two partially implantable magnetic bone-conduction devices for marketing through the 510(k) process:

- Otomag® Bone-Conduction Hearing System, Medtronic (formerly Sophono),
- Cochlear Baha® 4 Sound Processor, Cochlear Americas

The Bonebridge™ (MED-EL, Innsbruck, Austria) is another partially implantable bone-conduction implant that is considered an active transcutaneous device. It has been cleared for marketing in Europe but has not received FDA approval for use in the United States.

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. In 2011, it was cleared for marketing by FDA through the 510(k) process for indications similar to the Baha. Sonitus Medical closed in 2015.

For individuals who have unilateral sensorineural hearing loss who receive a fully or partially implantable BAHA with the contralateral routing of signal, the evidence includes a randomized controlled trial, 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, have generally reported improvements in patient-reported speech quality, speech perception in noise, and satisfaction with bone-conduction devices with contralateral routing of the signal. However, a well-conducted systematic review of studies comparing bone-anchored devices with hearing aids using contralateral routing of signal found no evidence of improvement in speech recognition or hearing localization. The single randomized controlled trial 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.

CODING

Commercial Products

The following CPT and HCPCS codes are medically necessary when filed with the ICD-10 diagnosis codes listed below. Any other diagnosis codes are not medically necessary.

69710 Implantation or replacement of electromagnetic bone-conduction hearing device in temporal bone
69711 Removal or repair of electromagnetic bone conduction hearing device in temporal bone
69714 Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715 Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; 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 Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
L8625 External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each (New code effective 1/1/18)
L8690 Auditory osseointegrated device, includes all internal and external components
L8691 Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
L8693 Auditory osseointegrated device abutment, any length, replacement only
L8694 Auditory osseointegrated device, transducer/actuator, replacement only, each

ICD 10 covered diagnosis codes
H60.60 – H60.93
H61.301 - H61.399
H65.20 - H65.499
H66.10 - H66.3X9
H90.0 - H90.8
Q16.0 - Q16.9

The following codes are covered.
L8618 Transmitter cable for use with cochlear implant device or auditory osseointegrated device, replacement
L8624 Lithium ion battery for use with cochlear implant or auditory osseointegrated device speech processor, ear level, replacement, each

RELATED POLICIES
Cochlear Implants
Hearing Aid Mandate
Semi and Fully Implantable Middle Ear Hearing Aids

PUBLISHED
Provider Update, December 2019
Provider Update, November 2018
Provider Update, January 2018
Provider Update, April 2017
Provider Update, August 2015

REFERENCES

1. Colquitt JL, Loveman E, Baguley DM, et al. Bone-anchored hearing aids for people with bilateral hearing impairment: a systematic review. Clin Otolaryngol. Oct 2011;36(5):419-441. PMID 21816006
2. 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. Jul 2011;15(26):1-200, iii-iv. PMID 21729632
3. Kompis M, Kurz A, Pfiffner F, et al. Is complex signal processing for bone conduction hearing aids useful? Cochlear Implants Int. May 2014;15 Suppl 1:S47-50. PMID 24869443
4. Hill-Feltham P, Roberts SA, Gladdis R. Digital processing technology for bone-anchored hearing aids: randomised comparison of two devices in hearing aid users with mixed or conductive hearing loss. J Laryngol Otol. Feb 2014;128(2):119-127. PMID 24524414
5. Farnoosh S, Mitsinikos FT, Maceri D, et al. Bone-anchored hearing aid vs. reconstruction of the external auditory canal in children and adolescents with congenital aural atresia: a comparison study of outcomes. Front Pediatr. 2014;2:5. PMID 24479110

6. Ramakrishnan Y, Marley S, Leese D, et al. Bone-anchored hearing aids in children and young adults: the Freeman Hospital experience. J Laryngol Otol. Feb 2011;125(2):153-157. PMID 20849670
7. den Besten CA, Harterink E, McDermott AL, et al. Clinical results of Cochlear BIA300 in children: Experience in two tertiary referral centers. Int J Pediatr Otorhinolaryngol. Dec 2015;79(12):2050-2055. PMID 26455259
8. McLarnon CM, Davison T, Johnson IJ. Bone-anchored hearing aid: comparison of benefit by patient subgroups. Laryngoscope. May 2004;114(5):942-944. PMID 15126761
9. Tringali S, Grayeli AB, Bouccara D, et al. A survey of satisfaction and use among patients fitted with a BAHA. Eur Arch Otorhinolaryngol. Dec 2008;265(12):1461-1464. PMID 18415113
10. 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. Feb 1995;28(1):73-83. PMID 7739870
11. van der Pouw CT, Snik AF, Cremers CW. The BAHA HC200/300 in comparison with conventional bone conduction hearing aids. Clin Otolaryngol Allied Sci. Jun 1999;24(3):171-176. PMID 10384840
12. Wazen JJ, Caruso M, Tjellstrom A. Long-term results with the titanium bone-anchored hearing aid: the U.S. experience. Am J Otol. Nov 1998;19(6):737-741. PMID 9831146
13. Granstrom G, Tjellstrom A. The bone-anchored hearing aid (BAHA) in children with auricular malformations. Ear Nose Throat J. Apr 1997;76(4):238-240, 242, 244-237. PMID 9127523
14. Janssen RM, Hong P, Chadha NK. Bilateral bone-anchored hearing aids for bilateral permanent conductive hearing loss: a systematic review. Otolaryngol Head Neck Surg. Sep 2012;147(3):412-422. PMID 22714424
15. Bosman AJ, Snik AF, van der Pouw CT, et al. Audiometric evaluation of bilaterally fitted bone-anchored hearing aids. Audiology. May-Jun 2001;40(3):158-167. PMID 11465298
16. Priwin C, Stenfelt S, Granstrom G, et al. Bilateral bone-anchored hearing aids (BAHAs): an audiometric evaluation. Laryngoscope. Jan 2004;114(1):77-84. PMID 14709999
17. Snik AF, Mylanus EA, Proops DW, et al. Consensus statements on the BAHA system: where do we stand at present? Ann Otol Rhinol Laryngol Suppl. Dec 2005;195:2-12. PMID 16619473
18. Dun CA, de Wolf MJ, Mylanus EA, et al. Bilateral bone-anchored hearing aid application in children: the Nijmegen experience from 1996 to 2008. Otol Neurotol. Jun 2010;31(4):615-623. PMID 20393374
19. Ho EC, Monksfield P, Egan E, et al. Bilateral bone-anchored hearing aid: impact on quality of life measured with the Glasgow Benefit Inventory. Otol Neurotol. Oct 2009;30(7):891-896. PMID 19692937
20. Briggs R, Van Hasselt A, Luntz M, et al. Clinical performance of a new magnetic bone conduction hearing implant system: results from a prospective, multicenter, clinical investigation. Otol Neurotol. Jun 2015;36(5):834-841. PMID 25634465
21. Denoyelle F, Coudert C, Thierry B, et al. Hearing rehabilitation with the closed skin bone-anchored implant Sophono Alpha1: results of a prospective study in 15 children with ear atresia. Int J Pediatr Otorhinolaryngol. Mar 2015;79(3):382-387. PMID 25617189
22. Hol MK, Nelissen RC, Agterberg MJ, et al. Comparison between a new implantable transcutaneous bone conductor and percutaneous bone-conduction hearing implant. Otol Neurotol. Aug 2013;34(6):1071-1075. PMID 23598702
23. Nelissen RC, Agterberg MJ, Hol MK, et al. Three-year experience with the Sophono in children with congenital conductive unilateral hearing loss: tolerability, audiometry, and sound localization compared to a bone-anchored hearing aid. Eur Arch Otorhinolaryngol. Oct 2016;273(10):3149-3156. PMID 26924741
24. Iseri M, Orhan KS, Tuncer U, et al. Transcutaneous bone-anchored hearing aids versus percutaneous ones: multicenter comparative clinical study. Otol Neurotol. Jun 2015;36(5):849-853. PMID 25730451

25. Gerdes T, Salcher RB, Schwab B, et al. Comparison of audiological results between a transcutaneous and a percutaneous bone conduction instrument in conductive hearing loss. Otol Neurotol. Jul 2016;37(6):685-691. PMID 27093021