

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



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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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Implantable bone-conduction and bone anchored hearing aids are covered.

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 6 System
 - BA310 Abutment, BIA310 Implant/Abutment
 - Baha 5 Power Sound Processor
 - Baha 5 Super Power Sound Processor
 - Baha® 5 Sound Processor
 - Baha® Attract System
 - Baha® Cordelle II

- Baha Divino®
- Baha Intenso® (digital signal processing)
- Baha® BP100
- Baha® 4 (upgraded from the BP100)
- Cochlear™ Osia™2 System
- OBC Bone-Anchored Hearing Aid System, manufactured by Oticon Medical
- Ponto Bone-Anchored Hearing System, manufactured by Oticon Medical
- Ponto 5 SuperPower, manufactured by Oticon Medical
- Ponto 4
- Ponto 3, Ponto 3 Power and Ponto 3 SuperPower

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 Osia™2 system may be used by adults and children 12 years of age and older with conductive hearing loss, mixed hearing loss, and single-sided sensorineural deafness.

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

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

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 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 have reported 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 an improvement in the net health outcome.

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

The following CPT and HCPCS code(s) are covered with no diagnosis edits for Medicare Advantage plans. For Commercial Products, the following CPT and HCPCS code(s) 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, skull with percutaneous attachment to external speech processor
- 69716** Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or resulting in removal of less than 100 sq mm surface area of bone deep to the outer cranial cortex
- 69717** Replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor
- 69719** Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex
- 69729** Implantation, osseointegrated implant, skull; with attachment to external speech processor, outside of the mastoid
- 69730** Replacement osseointegrated implant, skull; with attachment to external speech processor, outside the mastoid
- L8625** External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each
- 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 code(s) for Commercial Products only

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 code(s) are covered for Medicare Advantage Plans and Commercial Products:

- 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

PUBLISHED

Provider Update, April 2024
Provider Update, July 2023
Provider Update, October/December 2022
Provider Update, January/May 2021
Provider Update, December 2019

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