BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Implantable Bone Conduction and Bone-Anchored Hearing Aids (BAHA)

Policy #: 145
Category: Surgery

Latest Review Date: March 2020
Policy Grade: B

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after August 10, 2012:

Blue Advantage will treat **unilateral or bilateral fully or partially implantable bone-conduction (bone-anchored) hearing aid(s)** as a **covered benefit** as an alternative to an air-conduction hearing aid in patients **five years of age and older** with a **conductive or mixed hearing loss** who also meet **at least one** of the following medical 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); **and one of the following**:
  - Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear; **or**
  - Chronic external otitis or otitis media; **or**
  - Tumors of the external canal and/or tympanic cavity; **or**
  - Dermatitis of the external canal.

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 (4 kHz for OBC and Ponto Pro), or less than 15 dB at individual frequencies.

Blue Advantage will treat **an implantable bone-conduction (bone-anchored) hearing aid** as a **covered benefit** as an **alternative to an air-conduction contralateral routing of signal hearing aid** in patients **5 years of age and older with single-sided sensorineural deafness and normal hearing in the other ear.** The pure tone average air conduction threshold of the normal ear should be better than 20 dB measured at 0.5, 1, 2, and 3 kHz.

Blue Advantage will treat **other uses of implantable bone-conduction (bone-anchored) hearing aids**, including use in patients with bilateral sensorineural hearing loss, as a **non-covered benefit** and as **investigational**.

Non-osseointegrated hearing devices (e.g., BAHA Soft Band, SoundBite, Med-El Adhear) are not addressed in this medical policy since they are not osseointegrated. Please check benefit plan descriptions for hearing aid coverage.

Replacement for **lost** sound processors are noncovered. Members should contact the manufacturer for replacement under warranty or the manufacturer's replacement policy.

Replacement or upgrade of existing properly functioning durable medical equipment (including prosthetics), even if the warranty has expired is a **contract exclusion**.*

*Always check benefits for self-funded groups as it relates to contract exclusions.

Effective for dates of service on or after October 5, 2013:
Blue Advantage will treat **replacement upgraded processors** as a **covered benefit** when:

- A letter is received from the physician or audiologist requesting a replacement and
- The original processor is out of warranty and malfunctioning.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Sensorineural, conductive, and mixed hearing loss may be treated with a variety of devices, including conventional air-conduction (AC) or bone-conduction external hearing aids. AC hearing aids 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. 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 (BAHA) 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 in patients with unilateral single-sided sensorineural hearing loss.

Hearing Loss

Hearing loss is described as conductive, sensorineural, or mixed and can be unilateral or bilateral. Normal hearing is the detection of sound at or below 20 dB (decibel). The American Speech-Language-Hearing Association (ASLHA) has defined the degree of hearing loss based on pure-tone average (PTA) detection thresholds as mild (20 to 40 dB), moderate (40 to 60 dB), severe (60 to 80 dB), and profound ($\geq$80 dB). PTA is calculated by averaging the hearing sensitivities (i.e., 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 through the use of an air-conduction (AC) hearing aid can provide benefit to patients with sensorineural or mixed hearing loss. Contralateral routing of signal (CROS) is a system in which a microphone on the affected side transmits a signal to an air-conduction hearing aid on the normal or less affected side.

Treatment

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

A bone-anchored implant system works 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. Implantable bone-conduction hearing systems are primarily indicated for people with conductive or mixed sensorineural/conductive hearing loss. However, they may also be used with CROS as an alternative to an AC hearing aid with CROS for individuals with unilateral sensorineural hearing loss.

Partially implantable magnetic bone-conduction hearing system, also referred to as transcutaneous bone-anchored 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 magnets that adhere externally to magnets implanted in shallow bone beds with the bone-conduction hearing implant. Since the processor adheres magnetically to the implant, there is no need for a percutaneous abutment to physically connect the external and internal components. To facilitate greater transmission of acoustics between magnets, skin thickness may be reduced to 4 to 5 mm over the implant when it is surgically placed.

KEY POINTS:

This policy is updated regularly with searches of the MEDLINE database through December 9, 2019.

Summary of Evidence:

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

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

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 hearing assistance devices improve hearing to a greater degree than unilateral devices. BAHAs may be considered an alternative to external devices in patients who are not candidates for external devices. By extension, use of an implantable bone-conduction device with contralateral routing of signal may be considered in patients with unilateral sensorineural deafness.(See policy statement for coverage)

Practice Guidelines and Position Statements:
In 2016 the American Academy of Otolaryngology-Head and Neck Surgery updated its position statement on the use of implantable hearing devices. It states that the Academy "considers bone conduction hearing devices, including implantation of a percutaneous or transcutaneous device and use of a bone conduction oral appliance or bone conduction scalp device to be acceptable, and in many cases preferred, procedures in the treatment of conductive or mixed hearing loss and single-sided deafness when performed by a qualified otolaryngologist-head and neck surgeon."

U.S. Preventive Services Task Force Recommendations:
Not applicable.

KEY WORDS:
Bone conduction hearing aid, bone-anchored hearing aid (BAHA), implantable bone conduction hearing aid, air conduction hearing aid, single-sided deafness, and hearing aid, Otomag Sophono, partially implantable hearing aid, BAHA 4 Attract, BoneBridge™, BA310 Abutment, BIA 310 Implant/Abutment, Bonebridge, Baha 5 Super Power Sound Processor, Ponto 3, Ponto 4

APPROVED BY GOVERNING BODIES:
Several implantable bone-conduction hearing systems have been approved by the US Food and Drug Administration for marketing through the 510(k) process (Table 1).

Table 1. Implantable Bone-Conduction Hearing Systems Approved by the FDA

Device	Manufacturer	Date Cleared	510 (k) No.
Baha® Auditory Osseointegrated Implant System	Cochlear Americas		
BA310 Abutment, BIA 310 Implant/Abutment		December 2018	K182116
Baha 5 Power Sound Processor		May 2016	K161123
Baha 5 Super Power Sound Processor		May 2016	K153245
Baha® 5 Sound Processor		March 2015	K142907
Baha Attract System		November 2013	K131240
Baha® Cordelle II		April 2008	K080363
Baha Divino®		August 2004	K042017
Baha Intenso® (digital signal processing)		August 2008	K081606
Baha® 4 (upgraded from the BP100)		September 2013	K132278
OBC Bone-Anchored Hearing Aid System	Oticon Medical	November 2008	K112053
Ponto Bone-Anchored Hearing System	Oticon Medical	September 2012	K121228
Ponto 4		May 2019	
Ponto 3, Ponto 3 Power and Ponto 3 Super Power		September 2016	K161671

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 (i.e., single-sided deafness);
- Patients who are candidates for an AC CROS hearing aid but who cannot or will not wear an AC CROS device.

Baha sound processors can be used with the Baha® Softband™. With this application, there is no implantation surgery. The sound processor is attached to the head using a hard or soft headband. The amplified sound is transmitted transcutaneously to the cochlea via the bones of the skull. In 2002, the Baha® Softband™ was cleared for marketing by FDA for use in children younger than 5 years. Because this application has no implanted components, it is not addressed in this evidence review.

The FDA also cleared two partially implantable magnetic bone-conduction devices for marketing through the 510(k) process (Table 2)

Table 2. Partially Implantable Magnetic Bone-Conduction Devices Approved by the FDA

Device	Manufacturer	Date Cleared	510 (k) No.
Bonebridge	MED-EL	March 2019	K183373
Otomag® Bone-Conduction Hearing System	Medtronic (Formerly Sophono)	November 2013	K132189
Cochlear Baha® 4 Sound Processor	Cochlear Americas	October 2012	K121317

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 and was cleared for marketing through FDA's 510(k) clearance process in 2011 for similar indications as the BAHA. As of January 2015, Sonitus Medical is in bankruptcy.

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. In 2002, the BAHA® Softband™ was cleared for marketing by FDA for use in children younger than the age of 5 years. Because this application has no implanted components, it is not addressed in the policy.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

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
92626	Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); first hour
92627	; each additional 15 minutes (list separately in addition to code for primary procedure)

HCPC Codes:

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

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