MEDICAL POLICY

POLICY TITLE	IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES
POLICY NUMBER	MP-1.019

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**6/19/2018**
Effective Date:	**8/1/2018**

I. POLICY

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 who also meet at least **one** of the following medical criteria:

- 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;

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

An implantable bone-conduction (bone-anchored) hearing aid may be considered **medically necessary** as an alternative to an air-conduction CROS 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.

Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in patients with bilateral sensorineural hearing loss, are considered **investigational,** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

In patients being considered for implantable bone-conduction (bone-anchored) hearing aid(s), skull bone quality and thickness should be assessed for adequacy to ensure implant stability. Additionally, patients (or caregivers) must be able to perform proper hygiene to prevent infection and ensure the stability of the implants and percutaneous abutments.

Cross-reference:

MP-1.130 Semi-Implantable and Fully-Implantable Middle Ear Hearing Aid
MP-1.023 Cochlear Implants

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity. Bone anchored hearing aids (BAHAs) are eligible when medically necessary for members with traumatic injury or malformation of the external ear or middle ear (such as a surgically induced malformation or congenital malformation), limited to $1,000 per calendar year.

III. DESCRIPTION/BACKGROUND

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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 decibels (dB). The American Speech-Language-Hearing Association has defined degree of hearing loss based on pure-tone average detection thresholds as mild (20-40 dB), moderate (40-60 dB), severe (60-80 dB), and profound (≥80 dB). Pure-tone average is calculated by averaging hearing sensitivities (ie, the minimum volume that a patient hears) at multiple frequencies (perceived as pitch), typically within the range of 0.25 to 8 kHz.

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Sound amplification using 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 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 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 osseointegration through which living tissue integrates with titanium in the implant over 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.

REGULATORY STATUS

Six Baha® sound processors manufactured by Cochlear Americas (Englewood, CO) have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for use with the Baha auditory osseointegrated implant system:

- Baha® 5
- Baha® Cordelle II
- Baha Divino®
- Baha Intenso® (digital signal processing)
- Baha® BP100

- Baha® 4 (upgraded from the BP100).

FDA cleared the Baha system 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.

Other implantable bone-conduction hearing systems that rely on an abutment and have similar indications as the Cochlear Americas' Baha devices:

- OBC Bone-Anchored Hearing Aid System (Oticon Medical, Askim, Sweden). Cleared in November 2008.
- Ponto Bone-Anchored Hearing System (Oticon Medical). Cleared in September 2012. A next generation Ponto Pro device can be used with either Oticon or Baha implants.

Two partially implantable magnetic bone-conduction devices cleared by FDA through the 510(k) process are:

- Otomag® Bone-Conduction Hearing System (Sophono, Boulder, CO; now Medtronic, Minneapolis, MN),
- Cochlear Baha® 4 Attract System (Cochlear Americas, Centennial, CO).

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.

FDA product code (for bone-anchored hearing aid): LXB. FDA product code (for implanted bone conduction hearing aid): MAH.

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.

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have conductive or mixed hearing loss who receive an implantable 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 a meaningful 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 an RCT, 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 RCT 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.

V. DEFINITIONS

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HEARING AID is any device that does not produce as its output an electrical signal that directly stimulates the auditory nerve. Examples of hearing aids are devices that produce air-conducted sound into the external auditory canal, devices that produce sound by mechanically vibrating

bone, or devices that produce sound by vibrating the cochlear fluid through stimulation of the round window. Devices such as cochlear implants, which produce as their output an electrical signal that directly stimulates the auditory nerve, are not considered to be hearing aids.

OSSICLE refers to any small bone, especially one of the three bones of the ear.

SENSORINEURAL HEARING LOSS refers to a form of hearing loss in which sound is conducted normally through the external and middle ear but a defect in the inner ear or auditory nerve results in hearing loss. The loss is measured in decibels and may be described as mild, moderate, severe, or profound.

SUBCUTANEOUS refers to beneath the skin.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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Covered when medically necessary:

CPT Codes®								
69710	69711	69714	69715	69717	69718			

HCPCS Code	Description
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
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

ICD-10-CM Diagnosis Codes	Description
C30.1	Malignant neoplasm of middle ear
D23.21	Other benign neoplasm of skin of right ear and external auricular canal
D23.22	Other benign neoplasm of skin of left ear and external auricular canal
H60.61	Unspecified chronic otitis externa, right ear
H60.62	Unspecified chronic otitis externa, left ear
H60.63	Unspecified chronic otitis externa, bilateral
H61.311	Acquired stenosis of right external ear canal secondary to trauma
H61.312	Acquired stenosis of left external ear canal secondary to trauma
H61.313	Acquired stenosis of external ear canal secondary to trauma, bilateral
H61.321	Acquired stenosis of right external ear canal secondary to inflammation and infection
H61.322	Acquired stenosis of left external ear canal secondary to inflammation and infection
H61.323	Acquired stenosis of external ear canal secondary to inflammation and infection, bilateral
H61.391	Other acquired stenosis of right external ear canal
H61.392	Other acquired stenosis of left external ear canal
H61.393	Other acquired stenosis of external ear canal, bilateral
H65.21	Chronic serous otitis media, right ear
H65.22	Chronic serous otitis media, left ear
H65.23	Chronic serous otitis media, bilateral
H65.31	Chronic mucoid otitis media, right ear
H65.32	Chronic mucoid otitis media, left ear
H65.33	Chronic mucoid otitis media, bilateral
H65.411	Chronic allergic otitis media, right ear

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ICD-10-CM Diagnosis Codes	Description
C30.1	Malignant neoplasm of middle ear
H65.412	Chronic allergic otitis media, left ear
H65.413	Chronic allergic otitis media, bilateral
H65.491	Other chronic nonsuppurative otitis media, right ear
H65.492	Other chronic nonsuppurative otitis media, left ear
H65.493	Other chronic nonsuppurative otitis media, bilateral
H66.11	Chronic tubotympanic suppurative otitis media, right ear
H66.12	Chronic tubotympanic suppurative otitis media, left ear
H66.13	Chronic tubotympanic suppurative otitis media, bilateral
H66.21	Chronic atticoantral suppurative otitis media, right ear
H66.22	Chronic atticoantral suppurative otitis media, left ear
H66.23	Chronic atticoantral suppurative otitis media, bilateral
H66.3X1	Other chronic suppurative otitis media, right ear
H66.3X2	Other chronic suppurative otitis media, left ear
H66.3X3	Other chronic suppurative otitis media, bilateral
H71.11	Cholesteatoma of tympanum, right ear
H71.12	Cholesteatoma of tympanum, left ear
H71.13	Cholesteatoma of tympanum, bilateral
H90.0	Conductive hearing loss, bilateral
H90.11	Conductive hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.12	Conductive hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
H90.41	Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.42	Sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
H90.6	Mixed conductive and sensorineural hearing loss, bilateral
H90.71	Mixed conductive and sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.72	Mixed conductive and sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
H90.A11	Conductive hearing loss, unilateral, right ear with restricted hearing on the contralateral side
H90.A12	Conductive hearing loss, unilateral, left ear with restricted hearing on the contralateral side
H90.A31	Mixed conductive and sensorineural hearing loss, unilateral, right ear with restricted hearing on the contralateral side
H90.A32	Mixed conductive and sensorineural hearing loss, unilateral, left ear with restricted hearing on the contralateral side

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ICD-10-CM Diagnosis Codes	Description
C30.1	Malignant neoplasm of middle ear
L30.8	Other specified dermatitis
Q16.0	Congenital absence of (ear) auricle
Q16.1	Congenital absence, atresia and stricture of auditory canal (external)
Q16.3	Congenital malformation of ear ossicles
Q16.4	Other congenital malformations of middle ear
Q17.8	Other specified congenital malformations of ear

IX. REFERENCES

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X. POLICY HISTORY

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MP-1.019	**CAC 3/25/03**
	CAC 4/29/03
	CAC 7/27/04
	CAC 11/30/04
	CAC 9/27/05

POLICY TITLE	IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES
POLICY NUMBER	MP-1.019

	CAC 1/31/06
	CAC 1/30/07
	CAC 11/27/07
	CAC 11/25/08
	CAC 9/29/09 Consensus Review
	CAC 3/30/10 Policy criteria revised to include age parameters.
	CAC 4/26/11 Minor revision. Policy clarified to state that the bone-anchored hearing aid is a prosthetic device. Background revised to include new devices.
	CAC 10/25/11 Minor revision. Criteria for semi-implantable hearing aids was removed from this policy and placed in a separate policy, MP-1.130 Semi-Implantable and Fully Implantable Middle Ear Hearing Aid for Moderate to Severe Sensorineural Hearing Loss. No changes to policy statements.
	CAC 10/30/12 Consensus. References updated, no change to policy statements 10/19/12 codes reviewed
	CAC 11/26/13 BCBSA is being adopted for this review. Audiologic criteria have been added to the medically necessary statements for both unilateral and bilateral implantable bone-conduction (bone-anchored) hearing aid(s). A policy statement that partially implantable bone conduction hearing systems using magnetic coupling for acoustic transmission (e.g., Otomag Alpha 1 [M]) are considered investigational. Rationale and guidelines were added. References updated. Policy coded.
	CAC 11/25/14 Consensus review. Added BAHA attract to the last policy statement as an example of a partially implantable magnetic bone-conduction hearing system considered investigational. Rationale and references updated.
	CAC 11/24/15 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed and un-ranged.
	Admin update 1/1/17: Product variation section updated. New diagnosis codes added effective 10/1/16
	CAC 9/27/16 Minor review. Removed investigational statement for partially implantable devices. Background, rationale and references updated. Coding reviewed.
	CAC 9/26/17 Consensus. No change to policy statements. References and rationale updated. Coding reviewed.
	Admin Update 1/1/18: Updated L8691 with new description plus added L8618 and L8624; effective 1/1/18. Medicare variations removed from Commercial Policies.
	6/19/18 Consensus review. No changes to the policy statements. Background and rationale revised. References reviewed**.**

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