

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Implantable Bone-Conduction and Bone-Anchored Hearing Aids

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Policy Number: 479

BCBSA Reference Number: 7.01.03 (For Plan internal use only)

NCD/LCD: N/A

Related Policies

- Cochlear Implant, #478
- Semi-Implantable and Fully Implantable Middle Ear Hearing Aid #480

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Unilateral or bilateral fully or partially implantable bone-conduction (bone-anchored) hearing aid(s) may be <u>MEDICALLY NECESSARY</u> as an alternative to an air-conduction hearing aid in individuals 5 years of age and older with conductive or mixed hearing loss who also meets at least one of the following medical criteria:

- Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear
- Chronic external otitis or otitis media
- Tumors of the external canal and/or tympanic cavity, or
- Dermatitis of the external canal.

AND meets 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 (Baha 5, Ponto 4), 55 Db (Baha 6 Max, Baha 5 Power, Osia2, Ponto 3 Power) or 65 dB (Baha 5 SuperPower, Ponto 3 Superpower).

For bilateral implantation, individuals should meet the above audiologic criteria and have 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 Baha and Ponto Pro), or less than 15 dB at individual frequencies.

An implantable bone-conduction (bone-anchored) hearing aid may be <u>MEDICALLY NECESSARY</u> as an alternative to an air-conduction contralateral routing of signal hearing aid in individuals 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 bone-conduction (bone-anchored) hearing aids, including use in individuals with bilateral sensorineural hearing loss, are **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

Outpatient

• For services described in this policy, see below for products where prior authorization <u>might be required</u> if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue SM	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
69710	Implantation or replacement 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
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
69719	Osseointegrated implant revision or replacement with magnetic transcutaneous attachment to a speech processor
69726	Removal, entire osseointegrated implant, skull; with percutaneous attachment to external speech processor
69727	Removal, entire 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
69728	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex

69729	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
69730	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex

HCPCS Codes

HCPCS	
codes:	Code Description
L8690	Auditory osseointegrated device, includes all internal and external components

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT/HCPCS codes above if $\underline{\text{medical necessity criteria}}$ are met:

ICD-10 Diagnosis Codes

ICD-10-CM	Jnosis Codes
Diagnosis	
codes:	Code Description
C30.1	Malignant neoplasm of middle ear
C44.201	Unspecified malignant neoplasm of skin of unspecified ear and external auricular canal
C44.202	Unspecified malignant neoplasm of skin of right ear and external auricular canal
C44.209	Unspecified malignant neoplasm of skin of left ear and external auricular canal
H60.399	Other infective otitis externa, unspecified ear
H60.60	Unspecified chronic otitis externa, unspecified ear
H60.61	Unspecified chronic otitis externa, right ear
H60.62	Unspecified chronic otitis externa, left ear
H60.63	Unspecified chronic otitis externa, bilateral
H60.8x1	Other otitis externa, right ear
H60.8x2	Other otitis externa, left ear
H60.8x3	Other otitis externa, bilateral
H60.8x9	Other otitis externa, unspecified ear
H60.90	Unspecified otitis externa, unspecified ear
H60.91	Unspecified otitis externa, right ear
H60.92	Unspecified otitis externa, left ear
H60.93	Unspecified otitis externa, 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
H61.399	Other acquired stenosis of external ear canal, unspecified ear
H62.8x1	Other disorders of right external ear in diseases classified elsewhere
H62.8x2	Other disorders of left external ear in diseases classified elsewhere
H62.8x3	Other disorders of external ear in diseases classified elsewhere, bilateral
H62.8x9	Other disorders of external ear in diseases classified elsewhere, unspecified ear
H65.20	Chronic serous otitis media, unspecified ear
H65.21	Chronic serous otitis media, right ear
H65.22	Chronic serous otitis media, left ear
H65.23	Chronic serous otitis media, bilateral
H65.30	Chronic mucoid otitis media, unspecified ear
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
H65.412	Chronic allergic otitis media, left ear
H65.413	Chronic allergic otitis media, bilateral
H65.419	Chronic allergic otitis media, unspecified ear
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
H65.499	Other chronic nonsuppurative otitis media, unspecified ear
H66.10	Chronic tubotympanic suppurative otitis media, unspecified
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
H66.20	Chronic atticoantral suppurative otitis media, unspecified ear
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
H66.3X9	Other chronic suppurative otitis media, unspecified ear
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
H90.2	Conductive hearing loss, unspecified
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
	Mixed conductive and sensorineural hearing loss, unilateral, right ear, with
H90.71	unrestricted hearing on the contralateral side
H90.72	Mixed conductive and sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
H90.8	Mixed conductive and sensorineural hearing loss, unspecified
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.A21	Sensorineural hearing loss, unilateral, right ear, with restricted hearing on the contralateral side
H90.A22	Sensorineural 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, unilateral, left ear with restricted hearing on the contralateral side
Q16.1	Congenital absence, atresia and stricture of auditory canal (external)

Description

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 to 40 dB), moderate (40 to 60 dB), severe (60 to 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.

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. These 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.

Summarv

Sensorineural, conductive, and mixed hearing loss may be treated with various devices, including conventional air-conduction or bone-conduction external hearing aids. Air-conduction 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.

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-subject's 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 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. Quality RCTs on BAHA for unilateral sensorineural hearing loss are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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, the use of an implantable bone-conduction device with contralateral routing of the signal may be considered medically necessary in patients with unilateral sensorineural deafness.

Policy History

Date	Action
4/2024	Annual policy review. References updated. Policy statements unchanged.
4/2023	Annual policy review. Minor editorial refinements to policy statements; intent
	unchanged.
1/2023	Clarified coding information.
3/2022	Annual policy review. Policy statements unchanged.
1/2022	Clarified coding information.
7/2021	Clarification made to policy statement for FDA approved devices.
4/2021	Annual policy review. Description, summary, and references updated. Policy
	statements unchanged.
4/2020	Annual policy review. Description, summary, and references updated. Policy
	statements unchanged.
4/2019	Annual policy review. Description, summary, and references updated. Policy
	statements unchanged.
3/2017	Annual policy review. New references added.
12/2016	Annual policy review. Policy statements changed to remove investigational statement
	for partially implantable devices. References added. Clarified coding information
	Effective 12/1/2016.
8/2016	New medically necessary indications described for partially implantable bone
	conduction hearing systems using magnetic coupling for acoustic transmission.
	Effective 8/1/2016.
4/2016	Annual policy review. New references added.
2/2016	Clarified coding information.
3/2015	Annual policy review. New references added.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.

3/2014	Annual policy review. Investigational statement clarified. Effective 3/1/2014.
11/2013	Coding information clarified.
5/2013	Annual policy review. New references added.
2/2013	Annual policy review. New references added.
2007-2012	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to
	policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use

Managed Care Guidelines

Indemnity/PPO Guidelines

Clinical Exception Process

Medical Technology Assessment Guidelines

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