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Subject: Implantable Bone-Conduction and Bone-Anchored Hearing Aids

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	<u>Definitions</u>	Related Guidelines
<u>Other</u>	References	<u>Updates</u>			

DESCRIPTION:

Conventional external hearing aids can be generally subdivided into air conduction hearing aids and bone conduction hearing aids. Air conduction hearing aids require the use of ear molds, which 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. In these patients, bone conduction hearing aids may be an alternative. 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.

Bone-anchored hearing aids (BAHAs) are surgically implanted hearing devices that transmit sound directly to the inner ear through bone, bypassing the external auditory canal and middle ear. The BAHA system is composed of three main components: 1.) An internal titanium fixture that is surgically anchored to the skull in an area behind the ear; 2.) An external abutment that is connected to the implant at the time of surgery; and 3.) An external sound processor that is snapped on to the abutment. The sound processor vibrates the implant, which in turn vibrates the temporal bone. That vibration is then transmitted through other bones to the cochlea of the opposite ear, where it creates the sensation of sound. BAHAs are intended for use by patients who have conductive or mixed hearing loss.

Several implantable bone-conduction hearing systems have been approved by the U.S. Food and Drug Administration (e.g., Baha Divino®, OBC Bone-Anchored Hearing Aid System, Ponto Bone-Anchored Hearing System).

Summary and Analysis of Evidence: Boseman et al (2001) evaluated bilateral fittings of bone-anchored hearing aids (BAHA) in 25 patients with at least 3 months experience with using two BAHAs. For all patients, measurements comprised sound localization, speech recognition in quiet and in noise. In addition, in a subgroup of nine patients, release from masking for pure-tone stimuli in noise with interaural phase differences (binaural masking level difference. Binaural masking level difference (BMLD) was measured. The percentage of correct localization judgments with 500-Hz and 2-kHz noise bursts increased significantly (p<0.01) from 22.2 per cent and 24.3 per cent for unilateral fittings to 41.8 per cent and 45.3 per cent for bilateral fittings, respectively. The results for the six patients with congenital atresia are comparable with those for the other patients. So, directional hearing and speech recognition in noise improve significantly with a second BAHA. The BMLD measurements showed a significant (p<0.01) release from masking of 6.1, 6.0 and 6.6 dB for 125-Hz, 250-Hz and 500-Hz stimuli, respectively. The BMLD effect of 4.1 dB at 1,000 Hz was not significant at the 5 per cent level. The positive results with the bilateral fittings in quiet can be ascribed to increased stimulus levels due to diotic summation of signals from either side. The results for localisation, speech recognition in noise and BMLD measurements indicate that bilaterally fitted BAHAs do indeed (to some extent) result in binaural hearing.

Ellsperman et al (2021) Bone conduction is an efficient pathway of sound transmission which can be harnessed to provide hearing amplification. Bone conduction hearing devices may be indicated when ear canal pathology precludes the use of a conventional hearing aid, as well as in cases of single-sided deafness. Several different technologies exist which transmit sound via bone conduction. Surgically implanted bone conduction devices convert acoustic sound waves into mechanical vibration, which is conducted to the inner ear via direct contact with the skull. These can be classified broadly into percutaneous and transcutaneous devices based on the presence or absence of a skin-penetrating abutment. The transcutaneous devices can be further classified into active and passive implants. Passive transcutaneous devices have an implanted portion of the device in direct connection with the skull and a separate, external portion held in place magnetically which drives vibration through the skin to the implanted device. In a passive system, vibration occurs at the level of the external processor, and vibrations are transmitted transcutaneously to the implanted device. Active transcutaneous devices contain an external microphone and processor which send electronic signals to an implanted, vibrating device in direct contact with the skull. With an active system, the external processor is static and transmits electronic signals. Vibration occurs at the level of the implanted device only. Since the introduction of bone conduction hearing technology, numerous devices have been developed to optimize Signal transmission, limit skin and wound complications, and rehabilitate hearing for patients with conductive and mixed hearing loss and single-sided deafness.

POSITION STATEMENT:

A FDA approved unilateral or bilateral fully or partially implantable bone-conduction (bone-anchored) hearing aid **meets the definition of medical necessity** as a prosthetic device in members with conductive or mixed hearing loss who meet at least one of the following conditions and the audiologic criteria below:

- <u>Congenital</u> 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.

Audiologic criteria:

A pure-tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz or better than or equal to 45 dB (OBC and BP100 bone-anchored hearing aid devices), 55 dB (Intenso bone-anchored hearing aid device), or 65 dB (Cordele II bone-anchored hearing aid device).

Note: For bilateral implantation, members 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 OBC and Ponto Pro bone-anchored hearing aid device), or less than 15 dB at individual frequencies.

An implantable bone-conduction (bone-anchored) hearing aid **meets the definition of medical necessity** as an alternative to an air-conduction contralateral routing of signal (CROS) hearing aid in members 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.

An implantable bone-conduction (bone-anchored) hearing aid is considered **experimental or investigational** for all other indications when the criteria are not met, including, but not limited to use in individuals with bilateral <u>sensorineural hearing loss</u>. There is insufficient clinical evidence to support other uses of an implantable bone-conduction (bone-anchored) hearing aid, including use in individuals with bilateral sensorineural hearing loss.

BILLING/CODING INFORMATION:

CPT Coding:

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	Revision or 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

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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 Coding:

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
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
L8692	Auditory osseointegrated device, external sound processor, used without
	osseointegration, body worn, includes headband or other means of external
	attachment
L8693	Auditory osseointegrated device abutment, any length, replacement only
L8694	Auditory osseointegrated device, transducer/actuator, replacement only,
	each

ICD-10 Diagnosis Codes That Support Medical Necessity:

H60.60 – H60.63	Unspecified chronic otitis externa
H60.8x1 – H60.8x9	Other otitis externa
H60.90 – H60.93	Unspecified otitis externa
H61.391 – H61.399	Other acquired stenosis of external ear canal
H62.8x1 – H62.8x9	Other disorders of right external ear in diseases classified elsewhere

H64.491 – H64.499	Other chronic nonsuppurative otitis media
H65.20 – H65.23	Chronic serous otitis media
H65.30 – H65.33	Chronic mucoid otitis media
H65.411 – H65.419	Chronic allergic otitis media
H65.491 – H65.499	Other chronic nonsuppurative otitis media, unspecified ear
H65.90 – H65.93	Unspecified nonsuppurative otitis media
H66.001 – H66.009	Acute suppurative otitis media
H90.0	Conductive hearing loss, bilateral
H90.11 – H90.12	Conductive hearing loss, unilateral
H90.2	Conductive hearing loss, unspecified
H90.3	Sensorineural hearing loss, bilateral
H90.41 – H90.42	Sensorineural hearing loss, unilateral with unrestricted hearing on the
	contralateral side
H90.5	Unspecified sensorineural hearing loss
H90.6	Mixed conductive and sensorineural hearing loss, bilateral
H90.71 – H90.72	Mixed conductive and sensorineural hearing loss, unilateral with unrestricted
	hearing on the contralateral side
H90.8	Mixed conductive and sensorineural hearing loss, unspecified
Q16.1, Q16.3, Q16.4	Congenital malformations of ear causing impairment of hearing

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

Reimbursement for replacement of an implantable bone-conduction (bone-anchored) hearing aid(s) and its external components may be covered for any one of the following:

- When the existing device cannot be repaired; OR
- When replacement is required because a change in the individual's condition makes the present device non-functional and improvement is expected with a replacement device.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

Atresia: congenital absence or closure of a normal body orifice or tubular organ; the absence of closure of the external auditory meatus (ear canal).

Bilateral: pertaining to both sides (both ears).

Bone Anchored Hearing Aid (BAHA): A hearing device that is implanted in the bone of the skull and directly stimulates the cochlea.

Bone conduction: the conduction of sound to the inner ear through the bones of the skull.

Chronic: persisting over a long period of time.

Conductive hearing loss: a hearing loss that occurs when sound waves cannot transmit through the outer or middle ear or both.

Congenital: existing at, and usually before, birth; referring to conditions that are present at birth.

dB: decibel; unit for expressing the loudness of sound.

Dermatitis: inflammation of the skin.

Mixed hearing loss: a combination of sensorineural and conductive hearing loss.

Sensorineural hearing loss: a hearing loss that usually develops due to damage to the small sensory cells in the inner ear (hair cells).

Unilateral: affecting but one side (one ear).

RELATED GUIDELINES:

Prosthetics, 09-L0000-05

OTHER:

Other names used to report implantable bone conduction hearing aids:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Audiant Bone Conductor

Auditory osseointegrated implant system

Bone Anchored Hearing Aids (BAHA)

Electromagnetic bone conduction hearing device (e.g., Xomed)

Osseointegrated implant

The AudiantTM bone conductor is a type of electromagnetic bone conduction hearing device. While this device is no longer actively marketed, individuals with existing Audiant devices may require replacement, removal, or repair.

REFERENCES:

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- 3. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.03 Implantable Bone-Conduction and Bone-Anchored Hearing Aids, 03/25.
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- 5. Bradran K, Bunstone D, Arya AK et al. Patient satisfaction with the bone-anchored hearing aid: a 14-year experience. Otology & Neurotology 2006; 27(5): 659-666.
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- 13. U.S. Food and Drug Administration-Hearing Aids, 2018.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/26/25.

GUIDELINE UPDATE INFORMATION:

08/15/03	Annual review/new Medical Coverage Guideline. Implanted Devices for Hearing Loss and
	Aural Rehabilitation 02-69000-02, Archived.
12/15/05	Revised description section; description clarified to include Medtronic, Xomed, and BAHA.
	Revised ICD-9-CM diagnoses code description (380.15, 380.23), and updated references.
11/15/06	Added 69717 and 69718 to billing and coding information section. Added code descriptor
	for 382.1 – 382.9. Updated references.
01/01/07	Annual HCPCS coding update: Added L8690 and L8691.
05/15/07	MCG Archived.
01/01/08	Reinstated MCG. Added "Bone-Anchored" to guideline name. Reformatted guideline.
	Updated guideline, and updated references.

01/01/09	Scheduled review. No change in position statement, and updated references.
12/15/09	Annual review; no change in position statement, and updated references.
01/01/10	Annual HCPCS coding update: added code L8692.
04/15/10	Added ICD-9 diagnoses: 389.10, 389.11, 389.12, 389.13, 389.15, 389.17, 389.18, 389.20 –
	389.22, 744.02, and 744.04. Revised definitions and updated references.
01/01/11	Annual HCPCS coding update: added L8693.
01/15/11	Revision; related ICD-10 codes added.
09/15/11	Revised position statement; deleted wording: "as an alternative" and "to an air
	conduction hearing aid". Deleted "anchoring" from MCG subject. Added "anchored "to
	MCG subject.
12/01/11	Update; deleted ICD-9 code 774.02, added ICD-9 code 744.02, revised descriptor for ICD-9
	code 381.4 and 381.9 and added related ICD-10 codes.
05/11/14	Revision: Program Exceptions section updated.
10/01/15	Revision; updated ICD9 and ICD10 coding sections.
11/01/15	Revision: ICD-9 Codes deleted.
11/15/16	Revision; revised position statement and audiologic criteria. Updated references.
01/01/18	Annual HCPCS code update. Added L8618, L8624, L8625 and L8694. Revised L8691 code
	descriptor.
10/15/18	Review; no change to position statement. Updated references.
05/15/20	Review; no change to poition statement. Updated description and references.
01/01/22	Annual CPT/HCPCS coding update. Added 69716, 69719, 69726 and 69729. Revised 69714
	and 69717 code descriptor. Deleted 69715 and 69718.
06/15/22	Review; no change to position statement. Updated reference.
01/01/23	Annual CPT/HCPCS coding update. Added 69728, 69729 and 69730. Revised 69716,
	69717, 69719, 69726 and 69727 code descriptor.
08/21/23	Update to Program Exceptions section.
07/15/24	Review; no change to position statement. Updated reference.
07/15/25	Review; no change to position statement. Updated reference.