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Cochlear Implant and Implantable Bone Conduction Hearing Aids Corporate Medical Policy

File Name: Cochlear Implant & Implantable Bone Conduction Hearing Aids

File Code: 7.01.VT05 Origination: 03/2015 Last Review: 05/2023 Next Review: 05/2024 Effective Date: 06/01/2023

Description/Summary

Cochlear Implant

A cochlear implant is a device for treatment of severe-to-profound hearing loss in individuals who only receive limited benefit from amplification with hearing aids. A cochlear implant provides direct electrical stimulation to the auditory nerve, bypassing the usual transducer cells that are absent or nonfunctional in deaf cochlea.

For individuals who have bilateral sensorineural hearing loss who receive the cochlear implant(s), the evidence includes randomized controlled trials and multiple systematic reviews and technology assessments. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. The available studies have reported improvements in speech reception and quality of life measures. Although the available randomized controlled trials and other studies measured heterogeneous outcomes and included varying patient populations, the findings are consistent across multiple studies and settings. In addition to consistent improvement in speech reception (especially in noise), studies showed improvements in sound localization with bilateral devices. Studies have also suggested that earlier implantation may be preferred. 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 the cochlear implant(s), the evidence includes prospective and retrospective studies reporting withinsubjects comparisons and systematic reviews of these studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. Given the natural history of hearing loss, pre- and post-implantation comparisons may be appropriate for objectively measured outcomes. Clinical input received in 2021 strongly supports the use of cochlear implant in treatment of unilateral sensorineural hearing loss.

For individuals who have a high-frequency sensorineural hearing loss with preserved low-

Page 1 of 12

frequency hearing who receive a hybrid cochlear implant that includes a hearing aid integrated into the external sound processor of the cochlear implant, the evidence includes prospective and retrospective studies using single-arm, within-subject comparison pre- and postintervention and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. The available evidence has suggested that a hybrid cochlear implant system is associated with improvements in hearing of speech in quiet and noise. The available evidence has also suggested that a hybrid cochlear implant improves speech recognition better than a hearing aid alone. Some studies have suggested that a shorter cochlear implant insertion depth may be associated with preserved residual low-frequency hearing, although there is uncertainty about the potential need for reoperation after hybrid cochlear implantation if there is a loss of residual hearing. The evidence is insufficient to determine the effects of the technology on health outcomes. Clinical input obtained in 2016 has strongly supported the use of a hybrid cochlear implant for patients with high-frequency hearing loss but preserved low-frequency hearing

Implantable Bone-conduction hearing aids

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 prepost 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 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.

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

Coding Information

Click the links below for attachments, coding tables & instructions.

Attachment I - Procedural Coding Table & Instructions

When a service may be considered medically necessary

Cochlear Implant

Bilateral or unilateral cochlear implantation of a U.S. FDA-approved cochlear implant for the treatment of bilateral severe-to-profound sensorineural hearing loss may be considered **medically necessary** when **ALL** of the following criteria are met:

- In patients aged nine (9) months and older with bilateral severe-to-profound pre- or post-lingual (sensorineural) hearing loss, defined as a hearing threshold pure tone average of 70 dB hearing loss or greater at 500, 1000, and 2000 Hz;
 AND
- Who have shown limited or no benefit from hearing aids

Unilateral implantation of a U.S. FDA-approved implant for the treatment of single sided profound sensorineural hearing loss or asymmetrical hearing loss may be considered **medically necessary** when **ALL** of the following criteria are met:

- Patients aged one (1) year and older; AND
- Obtains limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted; AND
- At least one-month experience wearing and clinical benefit from a contralateral routing of signal (CROS) hearing aid or other relevant non implantable device; AND
- Any **ONE** of the following:
 - o Single-sided deafness (SSD) with profound sensorineural hearing loss in one

Page **3** of **12**

ear and normal hearing or mild sensorineural hearing loss in the other; OR Asymmetric hearing loss (AHL) with profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.

NOTE: For SSD and AHL indications, profound hearing loss is defined as having a pure tone average of 90 dB hearing loss or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Replacement of internal and/or external components is considered **medically necessary** only in a small subset of members who have inadequate response to existing component(s) to the point of interfering with the individual's activities of daily living, or the component(s) is/are no longer functional and cannot be repaired. Copies of original medical records must be submitted either hard copy or electronically to support medical necessity.

Cochlear implantation with a hybrid cochlear implant/hearing aid device that includes the hearing aid integrated into the external sound processor of the cochlear implant (e.g., the Nucleus® Hybrid™ L24 Cochlear Implant System) may be considered **medically necessary** for patients ages 18 years and older who meet all of the following criteria:

- Bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity; AND
- Receive limited benefit from appropriately fit bilateral hearing aids; AND
 - Have the following hearing thresholds:
 - Low-frequency hearing thresholds no poorer than 60 dB hearing level up to and including 500 Hz (averaged over 125, 250, and 500 Hz) in the ear selected for implantation; AND
 - Severe-to-profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥75 dB hearing level) in the ear to be implanted; AND
 - Moderately severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥60 dB hearing level) in the contralateral ear; AND
 - Aided consonant-nucleus-consonant word recognition score from 10% to 60% in the ear to be implanted in the preoperative aided condition and in the contralateral ear will be equal to or better than that of the ear to be implanted but not more than 80% correct.

Implantable Bone Conduction Devices

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 aged five (5) years of age and older with 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**

Page 4 of 12

- 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).

NOTE: For bilateral implantation, patients 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), 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 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.

When a service is considered not medically necessary

Replacement of internal and/or external components solely for the purpose of upgrading to a system with advanced technology or to a next-generation device is considered **not medically necessary.**

Upgrades of an existing, functioning external system to achieve aesthetic improvement, such as smaller profile components or a switch from a body-worn, external sound processor to a behind-the-ear model, are considered **not medically necessary**.

When a service is considered investigational

Cochlear implantation as a treatment for patients with tinnitus is considered investigational.

Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in patients with bilateral sensorineural hearing loss, are considered **investigational**.

When a service is considered non-covered, member contract exclusion

Communication devices and communication augmentation devices. Computer technology or accessories and other equipment, supplies or treatment intended primarily to enhance occupational, recreational or vocational activities, hobbies or academic performance.

Policy Guidelines

Bilateral cochlear implantation should be considered only when it has been determined

Page 5 of 12

that the alternative of unilateral cochlear implantation plus hearing aid in the contralateral ear will not result in a binaural benefit (i.e., in those patients with hearing loss of a magnitude where a hearing aid will not produce the required amplification).

In certain situations, implantation may be considered before 12 months of age. One scenario is post meningitis when cochlear ossification may preclude implantation. Another is in cases with a strong family history, because establishing a precise diagnosis is less uncertain.

Hearing loss is rated based on the threshold of hearing. Severe hearing loss is defined as a bilateral hearing threshold of 70 to 90 dB, and profound hearing loss is defined as a bilateral hearing threshold of 90 dB and above.

In adults, limited benefit from hearing aids is defined as scores of 50% correct or less in the ear to be implanted on tape recorded sets of open-set sentence recognition.

In children, limited benefit is defined as failure to develop basic auditory skills, and in older children, 30% or less correct on open-set tests.

A post cochlear implant rehabilitation program is necessary to achieve benefit from the cochlear implant. The rehabilitation program consists of 6 to 10 sessions that last approximately 2.5 hours each. The rehabilitation program includes development of skills in understanding running speech, recognition of consonants and vowels, and tests of speech perception ability.

Contraindications to cochlear implantation may include deafness due to lesions of the eighth cranial (acoustic) nerve, central auditory pathway, or brainstem; active or chronic infections of the external or middle ear; and mastoid cavity or tympanic membrane perforation. Cochlear ossification may prevent electrode insertion, and the absence of cochlear development as demonstrated on computed tomography scans remains an absolute contraindication.

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.

Reference Resources

- 1. Blue Cross Blue Shield Association Medical Policy Manual, Policy Number: 7.01.05 Cochlear Implant. Last reviewed March, 2023. Accessed April, 2023.
- Blue Cross Blue Shield Association Medical Policy Manual, Policy Number: 7.01.03

 Implantable Bone-Conduction and Bone-Anchored Hearing Aids. Last reviewed
 March 2023. Accessed April 2023.
- 3. Benchetrit L, Ronner EA, Anne S, Cohen MS. Cochlear Implantation in Children With Single-Sided Deafness: A Systematic Review and Meta-analysis. *JAMA Otolaryngol Head Neck Surg.* 2021;147(1):58-69. doi:10.1001/jamaoto.2020.3852
- 4. Deep NL, Gordon SA, Shapiro WH, Waltzman SB, Roland JT Jr, Friedmann DR. Cochlear Implantation in Children with Single-Sided Deafness. Laryngoscope. 2021 Jan;131(1):E271-E277. doi: 10.1002/lary.28561. Epub 2020 Feb 17. PMID: 32065422.
- 5. Warner-Czyz, Andrea D.1; Roland, J. Thomas Jr2; Thomas, Denise3; Uhler,

- Kristin4,5; Zombek, Lindsay6 American Cochlear Implant Alliance Task Force Guidelines for Determining Cochlear Implant Candidacy in Children, Ear and Hearing: March/April 2022 Volume 43 Issue 2 p 268-282
- 6. UpToDate. Hearing Loss in Children: Treatment. Literature review current through 3/2023. Accessed 4/2023.

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non- compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval may be required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy

Page **7** of **12** Medical Policy Number: 7.01.VT05 when there is a conflict.

Policy Implementation/Update information

212211	
8/2011	(Incorporated some language and coding from Evaluation of Hearing Medical Policy) Coding is appropriate per Medical/Clinical Coder SAR
11/2012	Font and format changes. Added Audiologists back into the policy. Added "Audit Information" section. Coding table reformatted. RLJ
03/2015	Adoption of BCBSA policy 7.01.05 Cochlear implants. Aural rehabilitation codes remain in policy.
05/2016	Policy updated with literature review through April 19, 2015; references 17, 23-24, 36-37, and 45 added. Policy statements unchanged
10/2016	Policy updated with results of clinical input. Policy statement changed to indicate that cochlear implantation with a hybrid cochlear implant/hearing aid system is considered medically necessary for patients meeting criteria.
01/2019	Policy updated to reflect BCBSA MPRM 07.01.05. No substantial change to policy statement. Updated references.
10/2019	Policy updated to add BCBSA MPRM 07.01.03 and update 07.01.05. Additions to policy statement for Implantable Bone Conduction hearing aids and updated references. Codes added to coding table: 69710, 69711, 69714, 69715, 69717, 69718, L8625, L8690, L8691, L8692, L8693 & L8694 require prior approval.
01/2021	Policy reviewed. Minor formatting changes. References Reviewed. Policy statement updated to reflect expanded indications in children aged 9-12 months with profound bilateral sensorineural hearing loss, consistent with BCBSA 7.01.05.
12/2021	Adaptive Maintenance Review: Effective 01/01/2022 Deleted codes: 69715 & 69718. Added codes 69716, 69719, 69726 & 69727 as requiring prior approval. Revised descriptors for codes 69714 & 69717.
06/2022	Policy Reviewed. External feedback received. Added medical necessity criteria for the use of cochlear implants for the treatment of single-sided profound sensorineural hearing loss. Use of cochlear implant for treatment of tinnitus remains investigational. Minor formatting and language changes. References updated.
12/2022	Adaptive Maintenance Effective 01/01/2023: Updated the following code descriptors: 69716, 69717, 69719, 69726, 69727. Added codes 69728, 69729, 69730 as requiring prior approval.
05/2023	Policy Reviewed. Added clarification to policy statement for unilateral cochlear implants.

Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors

Date Approved

Tom Weigel, MD, MBA Vice President & Chief Medical Officer

Page 8 of 12

Attachment I Procedural Coding Table & Instructions

Code Type	Number	Description	Policy Instructions		
	The following codes will be considered as medically necessary when applicable criteria have been met.				
CPT [®]	69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone	Prior Approval Required		
CPT [®]	69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone	Prior Approval Required		
CPT [®]	69714	Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor	Prior Approval Required		
CPT [®]	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 sp mm surface area of bone deep to the outer cortex	Prior Approval Required		
CPT [®]	69717	Replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor	Prior Approval Required		
CPT [®]	69719	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	Prior Approval Required		
CPT [®]	69726	Removal, entire osseointegrated implant, skull; with percutaneous attachment to external speech processor	Prior Approval Required		
CPT [®]	69727	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	Prior Approval Required		
CPT®	69728	Removal, osseointegrated implant, skull; with attachment to external speech processor, outside the mastoid	Prior Approval Required		
CPT®	69729	Implantation, osseointegrated implant, skull; with attachment to external speech processor, outside of the mastoid	Prior Approval Required		

CPT®	69730	Replacement osseointegrated implant, skull; with attachment to external speech processor, outside the mastoid	Prior Approval Required
CPT®	69930	Cochlear device implantation, with or without mastoidectomy	Prior Approval Required
CPT [®]	92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual	
CPT ®	92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming	
CPT [®]	92602	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent programming	
CPT [®]	92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming	
CPT [®]	92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming	
CPT [®]	92626	Evaluation of auditory rehabilitation status, first hour	
CPT [®]	92627	Evaluation of auditory rehabilitation status, each additional 15 minutes (Use in conjunction with 92626)	
CPT [®]	92630	Auditory rehabilitation, prelingual hearing loss	
CPT [®]	92633	Auditory rehabilitation, postlingual hearing loss	
HCPCS	L8614	Cochlear device; includes all internal and external components	Prior Approval Required
HCPCS	L8615	Headset/headpiece for use with cochlear implant device, replacement	Prior Approval Required
HCPCS	L8616	Microphone for use with cochlear implant device, replacement	Prior Approval Required
HCPCS	L8617	Transmitting coil for use with cochlear implant device, replacement	Prior Approval Required
HCPCS	L8618	Transmitter cable for use with cochlear implant device, replacement	Prior Approval Required

HCPCS	L8619	cochlear implant, external speech processor and controller, integrated system, replacement	Prior Approval Required	
HCPCS	L8621	Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each	- 1	
HCPCS	L8622	Alkaline battery for use with cochlear implant device, any size, replacement, each		
HCPCS	L8623	Lithium ion battery for use with cochlear implant device speech processor, other than ear level, replacement, each		
HCPCS	L8624	Lithium ion battery for use with cochlear implant device speech processor, ear level, replacement, each		
HCPCS	L8625	External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only	Prior Approval Required	
HCPCS	L8627	Cochlear implant, external speech processor, component, replacement	Prior Approval Required	
HCPCS	L8628	Cochlear implant, external controller component, replacement	Prior Approval Required	
HCPCS	L8629	Transmitting coil and cable, integrated, for use with cochlear implant device, replacement	Prior Approval Required	
HCPCS	L8690	Auditory osseointegrated device, includes all internal and external components	Prior Approval Required	
HCPCS	L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each	Prior Approval Required	
HCPCS	L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment	Prior Approval Required	
HCPCS	L8693	Auditory osseointegrated device abutment, any length, replacement only	Prior Approval Required	
HCPCS	L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each	Prior Approval Required	
The following codes will be denied Not Medically Necessary, Investigational or Contract Exclusions				

CPT®	92605	Evaluation for prescription of non- speech- generating augmentative and alternative communication device.	Contract Exclusion
CPT®	92606	Therapeutic service(s) for the use of non- speech- generating device, including programming and modification	Contract Exclusion
CPT®	92607	Evaluation for prescription for speech- generating augmentative and alternative communication device, face- to-face with the patient; first hour	Contract Exclusion
CPT®	92608	Evaluation for prescription for speech- generating augmentative and alternative communication device, face- to-face with the patient; each additional 30 minutes	Contract Exclusion
CPT®	92609	Therapeutic services for the use of speech generating device, including programming and modification	Contract Exclusion
HCPCS	V5273	Assistive listening device, for use with cochlear implant	Contract Exclusion