Clinical Policy Title: Bone-anchored hearing aids and cochlear implants

Clinical Policy Number: 10.03.02

Effective Date:	**June 1, 2014**
Initial Review Date:	January 15, 2014
Most Recent Review Date:	January 11, 2018
Next Review Date:	January 2019

Policy contains:

- Conductive hearing loss.
- Sensorineural hearing loss.
- Children and adults.
- Uni- or bilateral hearing loss.

Related policies:

None.

ABOUT THIS POLICY: *AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.*

Coverage policy

AmeriHealth Caritas considers the use of bone-anchored hearing aids and cochlear implants to be clinically proven and, therefore, medically necessary when the following criteria are met (Hayes 2016, Blasco 2014, McCreery 2012, Black 2011, Cincinnati Children's Hospital 2011, Colquitt 2011, Summerfield 2010, Bond 2009, UK National Institute for Health and Clinical Excellence 2009):

Bone-anchored hearing aids:

Post-lingual (> five years) and uni- or bilateral conductive or mixed (conductive and sensorineural) hearing loss, where conventional air conduction hearing aid is ineffective or contraindicated, and any of the following conditions are present:

- Congenital or surgically induced external ear canal or middle ear malformation.
- External ear dermatitis, including hypersensitivity reaction to conventional hearing aid.
- Hearing loss secondary to otosclerosis that is not amenable to surgical correction.
- Severe chronic otitis externa or otitis media.
- External ear canal or tympanic cavity tumors.

- Other contraindications to conventional hearing aid use.

Cochlear implants:

- Unilateral implantation: severe or profound deafness and inadequate benefit from conventional, acoustic hearing aids.
- Bilateral implants: severe or profound deafness in children; adults who are blind or have other disabilities and must increasingly rely on auditory stimuli for spatial awareness.

Limitations:

Either device only after assessment and documentation by multidisciplinary team.

- Three-month trial of conventional hearing aid.
- Treatment center manages at least 15 new cases per year.

There is no literature to support that this service is medically necessary for isolated sensorineural hearing loss.

Alternative covered services:

Physician office visits and speech therapy.

Background

Hearing loss, impairment, or deafness are among the most common sensory disorders. Hearing loss can present at any age and is experienced by approximately 10 percent of adults. One-third of those over age 65 have losses sufficient to need hearing aids. It can be associated with age, noise exposure, physical or chemical trauma, or disease (including genetic and infectious). It is generally classified as conductive or sensorineural.

Hearing loss can result from disorders (along the normal pathway) for transmission of sound into electrical energy, from the auricle (external ear), external auditory canal, and middle and inner ears to the central auditory pathways in the brain. Disruptions along the normal pathway are considered conductive hearing loss.

Sensorineural hearing loss involves deficits associated with the vestibulocochlear nerve (cranial VII), the inner ear and/or central brain processing centers. In many cases, the problem can be localized to hair cells in the organ of Corti within the cochlea.

Conductive hearing loss often is amenable to surgical correction, while sensorineural losses are more difficult to manage. Mild, moderate, or even more severe sensorineural losses are regularly rehabilitated with hearing aids of varying strength and configuration; the current generation is

miniaturized for placement entirely within the ear canal, thus avoiding stigma associated with use. People with unilateral loss often have difficulty with localization and reduced clarity in background noise; they may benefit from a contralateral routing of signals aid, in which a microphone of the impaired side transmits to a receiver on the other. Bone-anchored hearing aids achieve a similar result by vibrating the skull. Patients with profound deafness on one side and some loss on the other may be candidates for a bilateral contralateral routing of signals aid, in which the patient wears a hearing aid rather than a receiver in the better ear. Even these relatively sophisticated technologies may be judged unsatisfactory by patients.

Bone-anchored hearing aids transmit sound vibration to the inner ear by direct bone conduction through the skull. Bone-anchored hearing aids improve acuity in moderate to severe conductive or mixed hearing loss and are a sound alternative to patients who are unable to use, or dissatisfied with, conventional air conduction hearing aids.

Cochlear implants are used in patients with bilateral hearing impairment due to severe loss of cochlear hair cells. Implants restore hearing by converting sound into electrical impulses that stimulate the auditory nerve (functions normally performed by hair cells). Implantation may be uni- or bilateral, with the latter intending to more closely simulate normal hearing.

Arguments against bilateral implants (simultaneous or sequential) include:

- Preserving contralateral ear for future technology.
- Damage to residual hearing (implants destroy hair cells).
- Additional anesthesia.
- Potential harm to vestibular system.

Cincinnati Children's Hospital (2011, Summary of Clinical Evidence table below) concludes that concerns have been addressed. Implantation in children is reliable and safe in experienced hands and has a low rate of serious complications. However, costs to hospital and family (including the device and accessories, follow-up therapy, programming sessions, and lifelong support) warrant further investigation.

Frequency modulation hearing-assistive systems are miniature radio stations operating on special frequencies. The personal frequency modulation system consists of a transmitter microphone used by a speaker (typically a classroom teacher or lecturer) and a receiver used by the listener, which transmits sound directly to the ear, hearing aid, cochlear implant, or headset.

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.

- Agency for Healthcare Research and Quality's National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on November 20, 2017. Search terms were: "bone-anchored hearing aid," "cochlear implant," and "frequency modulation system."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Bone-anchored hearing aids

- While available evidence is methodologically weak, bone-anchored hearing aids improve hearing and quality of life compared to unaided hearing.
- There is some evidence for additional benefits from bilateral versus unilateral bone-anchored hearing aids.

Cochlear implants:

- Cochlear implantation requires complex case evaluation, surgery, and rehabilitation; however, unilateral implantation is generally safe and effective for children and adults with severe or profound post-lingual hearing loss.
- Bilateral implants may confer additional benefits.
- Outcomes vary due to a broad spectrum of adverse influences.

Frequency modulation systems: represented by one systematic review (McCreery, 2012) that found limited evidence for strong conclusions for (or against) use in school-aged children.

Hayes (2016) reports there is a small amount of literature available pertaining to the Ponto bone conduction hearing device. No reports were found that reported outcomes in the abstracts for the Ponto Plus device specifically or that addressed the use of this device for unilateral mixed hearing loss. Overall, the literature was of poor quality and the studies had small sample sizes.

Policy updates:

A systematic review (Blasco 2014) sought to understand the role of cochlear implantation for unilateral hearing loss. Subjects were included for analysis only if the course of hearing loss was acute and rapidly progressive, if the loss was severe to profound, and if the contralateral ear had normal hearing. Subjective changes of tinnitus in 27 patients, speech understanding in 16 patients, and sound localization in 16 patients found 96 percent, 100 percent, and 87 percent were improved, respectively. The authors concluded that cochlear implantation in unilateral sudden hearing loss with a normal functioning contralateral ear is an effective therapy. Tinnitus is reduced as is the signal-to-noise ratio, which still allows 50 percent speech discrimination. All patients felt that they localized sound better, and most felt that they understood speech better.

Summary of clinical evidence:

Citation	Content, Methods, Recommendations
Hayes (2016) Ponto Plus bone-anchored hearing aid (Oticon) for unilateral mixed hearing loss	Key points: • The Ponto System can be used for single-sided deafness or fitted bilaterally on both ears. It consists of three parts: - A small 3 – 4 mm titanium implant that sits in the bone behind the ear. - The abutment where the sound processor is attached. - The Ponto sound processor. • It is intended for improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness. • There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management with the Ponto Plus bone-anchored hearing aid for the treatment of unilateral mixed hearing loss.
Blasco (2014) Cochlear implantation in unilateral sudden deafness improves tinnitus and speech comprehension: meta-analysis and systematic review.	Key points: • Systematic review sought to understand the role of cochlear implantation for unilateral hearing loss. • Subjects were included for analysis only if the course of hearing loss was acute and rapidly progressive, if the loss was severe to profound, and if the contralateral ear had normal hearing. • Subjective changes of tinnitus in 27 patients, speech understanding in 16 patients, and sound localization in 16 patients found 96 percent, 100 percent, and 87 percent were improved, respectively. • The authors concluded that cochlear implantation in unilateral sudden hearing loss with a normal functioning contralateral ear is an effective therapy. • Tinnitus is reduced as is the signal-to-noise ratio, which still allows 50 percent speech discrimination. • All patients felt that they localized sound better, and most felt that they understood speech better.

Citation	Content, Methods, Recommendations
Hayes (2013) Bilateral cochlear implantation in adults	Key points: • Bilateral cochlear implantation in adults. • Substantial body of evidence: second cochlear implant in adults with severe or profound post-lingual sensorineural loss, which improves speech perception and localization in noise conditions, but studies did not evaluate language proficiency. • Several small studies for functional improvement or life quality. • Post-procedure auditory rehabilitation required.
Hayes (2013a) Bilateral cochlear implantation in children	Key points: • Bilateral cochlear implantation in children. • Substantial evidence that bilateral implantation improves speech perception and localization versus single implantation for children and adolescents with severe or profound post-lingual bilateral deafness who will receive post-procedure auditory rehabilitation and have no other significant disabilities or structural abnormalities.
McCreery (2012) An evidence-based systematic review of directional microphones and digital noise reduction hearing aids	Key points: • Directional microphones and digital noise reduction hearing aids in school-aged children. • Randomized controlled trials, 1980. • Four noise reduction and seven directional microphone studies in nine articles, none of which reported audibility outcomes. • Digital noise reduction did not improve or degrade speech recognition; complex learning tasks were unaffected. • Directional microphones improved speech recognition in controlled settings with the speaker in front of the listener. • Overall, evidence of low or moderate quality, with additional research needed.
Black (2011) Prognostic indicators in pediatric cochlear implant surgery	Key points: • Prognostic indicators for pediatric cochlear implants. • Heterogeneity precluded meta-analysis. • Few eligible well-conducted studies: only four adverse indicators identified: age at implantation; connexin 26; inner ear malformations; meningitis. • Relevant adverse factors largely unreported.
Cincinnati Children's Hospital (2011) Quality of life in children with sequential bilateral cochlear implants	Key points: • Quality of life in children with sequential bilateral cochlear implants. • Best evidence for domain, 2010. • Insufficient evidence for sequential versus unilateral to improve quality of life.

Citation	Content, Methods, Recommendations
Colquitt (2011) Bone-anchored hearing aids	Key points: • Bone-anchored hearing aids for bilateral deafness. • Prospective comparisons with conventional hearing aids, unaided hearing, or surgery, November 2009. • Available evidence methodologically weak. • Hearing and quality of life improved versus unaided. • Some evidence for bilateral versus unilateral.
Summerfield (2010) Estimates of the cost effectiveness of pediatric bilateral cochlear implantation	Key points: • Cost effectiveness of pediatric bilateral cochlear implants. • Potentially cost effective for young deaf children, but with considerable uncertainty in quality of life estimates.
Bond (2009) The effectiveness and cost effectiveness of cochlear implants	Key points: • Cochlear implants for severe to profound deafness in children > 12 months and adults. • Despite reservations re: study quality: unilateral implantation is safe and effective; bilateral may provide additional gain.
UK National Institute for Health and Clinical Excellence (NICE) (2009) Cochlear implants for children and adults with severe to profound deafness	Key points: • Cochlear Implants for children and adults with severe to profound deafness. • Systematic reviews and randomized controlled trials, July 2007. • Unilateral implantation: an option for people with severe or profound deafness and inadequate benefit from conventional acoustic hearing aids. • Bilateral implants: severe or profound deafness in children; adults who are blind or have other disabilities; increasing reliance on auditory stimuli for spatial awareness. • Implantation only after assessment by multidisciplinary team and after three-month trial of conventional hearing aid.

References

Professional society guidelines/other:

Cincinnati Children's Hospital Medical Center. Best evidence statement (BESt). *Quality of life in children with sequential bilateral cochlear implants*. Cincinnati (OH): Cincinnati Children's Hospital Medical Center. 2011.

Hayes, Inc. Bilateral cochlear implantation in adults. Hayes Directory pocket summary. July 15, 2013.

Hayes, Inc. Bilateral cochlear implantation in children. Hayes Directory pocket summary. July 15, 2013a.

Hayes, Inc. Ponto Plus Bone-Anchored Hearing Aid (Oticon) for Unilateral Mixed Hearing Loss. Hayes search and summary. May 26, 2016.

National Institute for Health and Clinical Excellence. *Cochlear implants for children and adults with severe to profound deafness*. London: National Institute for Health and Clinical Excellence (NICE). Technology Appraisal Guidance 166.2009.

Peer-reviewed references:

Black J, Hickson L, Black B, Perry C. Prognostic indicators in pediatric cochlear implant surgery: a systematic literature review. *Cochlear Implants Int.* 2011; 12(2):67-93.

Blasco MA, Redleaf MI. Cochlear implantation in unilateral sudden deafness improves tinnitus and speech comprehension: meta-analysis and systematic review. *Otol Neurotol*. 2014;35(8):1426-32.

Bond M, Mealing S, Anderson R, et al. The effectiveness and cost-effectiveness of cochlear implants for severe to profound deafness in children: a systematic review and economic model. *Health Techno Assess.* 2009; 13(44):199-211.

Colquitt JL, Jones J, Harris P, Loveman E, Bird A, Clegg AJ, Baguley DM, Proops DW, Mitchell TE, Sheehan PZ, Welch K. Bone-anchored hearing aids (BAHAs) for people who are bilaterally deaf: a systematic review and economic evaluation. *Health Technol Assess.* 2011; 15(26):1-194.

Gaylor JM, Raman G, Chung M, et al. Cochlear implantation in adults: a systematic review and meta-analysis. *Otolaryngol Head Neck Surg.* 2013;139(3):265-72.

Kiringoda R, Lustig LR. A meta-analysis of the complications associated with osseointegrated hearing aids. *Otol Neurotol*. 2013;34(5):790-94.

Lin FR, Niparko JK, Francis HW. Outcomes in cochlear implantation: assessment of quality of life impact and economic evaluation of the cochlear implant. In: Eisenberg LS(ed.). *Clinical Management of Children with Cochlear Implants* (2nd edition).San Diego, USA: Plural Publishing.2009.

McCreery RW, Venediktov RA, Leech HM. An evidenced-based systematic review of directional microphones and digital noise reduction hearing aids in school-age children with hearing loss. *Am J Audiol.* 2012; 21(2):295-312).

Santa Maria PL, Gluth MB, Yuan Y, Atlas MD, Blevins NH. Hearing preservation surgery for cochlear implantation: a meta-analysis. *Otol Neurotol.* 2014;35(10):e256-69.

Sparreboom M, van Schoonhoven J, van Zanten BG, et al. The effectiveness of bilateral cochlear implants for severe-to-profound deafness in children: a systematic review. *Otol Neurotol*.2010;31(7):1062-71.

Summerfield AQ, Lovett RE, Bellinger H, Batten G. Estimates of the cost-effectiveness of pediatric bilateral cochlear implantation. *Ear Hear.*2010; 31(5):611-24.

CMS National Coverage Determinations (NCDs):

50.3 NCD: Cochlear implantation. CMS Medicare Coverage Database website. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=245&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=cochlear+implant&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAACAAAAAAAA%3d%3d&. Accessed November 14, 2017.

Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

CPT Code	Description	Comments
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	
69930	Cochlear device implantation with or without mastoidectomy	

ICD-10 Code	Description	Comments
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	
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck	
C79.2	Secondary malignant neoplasm of skin	
D04.20	Carcinoma in situ of skin of unspecified ear and external auricular canal	
D04.21	Carcinoma in situ of skin of right ear and external auricular canal	
D04.22	Carcinoma in situ of skin of left ear and external auricular canal	
D14.0	Benign neoplasm of middle ear, nasal cavity and accessory sinuses	
D23.20	Other benign neoplasm of skin of unspecified ear and external auricular canal	
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	
D48.5	Neoplasm of uncertain behavior of skin	
D49.2	Neoplasm of unspecified behavior of bone, soft tissue, and skin	
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	
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	
H80.00	Otosclerosis involving oval window, nonobliterative, unspecified ear	
H80.01	Otosclerosis involving oval window, nonobliterative, right ear	
H80.02	Otosclerosis involving oval window, nonobliterative, left ear	
H80.03	Otosclerosis involving oval window, nonobliterative, bilateral	
H80.10	Otosclerosis involving oval window, obliterative, unspecified ear	
H80.11	Otosclerosis involving oval window, obliterative, right ear	
H80.12	Otosclerosis involving oval window, obliterative, left ear	
H80.13	Otosclerosis involving oval window, obliterative, bilateral	
H80.20	Cochlear otosclerosis, unspecified ear	
H80.21	Cochlear otosclerosis, right ear	
H80.22	Cochlear otosclerosis, left ear	
H80.23	Cochlear otosclerosis, bilateral	
H80.80	Other otosclerosis, unspecified ear	
H80.81	Other otosclerosis, right ear	

ICD-10 Code	Description	Comments
H80.82	Other otosclerosis, left ear	
H80.83	Other otosclerosis, bilateral	
H80.90	Unspecified otosclerosis, unspecified ear	
H80.91	Unspecified otosclerosis, right ear	
H80.92	Unspecified otosclerosis, left ear	
H80.93	Unspecified otosclerosis, 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	
H90.2	Conductive hearing loss, unspecified	
H90.3	Sensorineural hearing loss, bilateral	
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	
H90.5	Unspecified sensorineural hearing loss	
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	
H90.8	Mixed conductive and sensorineural hearing loss, unspecified	
H91.90	Unspecified hearing loss, unspecified ear	
H91.91	Unspecified hearing loss, right ear	
H91.92	Unspecified hearing loss, left ear	
H91.93	Unspecified hearing loss, bilateral	
H93.3X1	Disorders of right acoustic nerve	
H93.3X2	Disorders of left acoustic nerve	
H93.3X3	Disorders of bilateral acoustic nerves	
L24.9	Irritant contact dermatitis, unspecified cause	
L25.9	Unspecified contact dermatitis, unspecified cause	
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	
Q16.5	Congenital malformation of inner ear	
Q16.9	Congenital malformation of ear causing impairment of hearing, unspecified	
Z90.09	Acquired absence of other part of head and neck	

HCPCS Level II Code	Description	Comments
L8690	Auditory osseointegrated device: internal and external components	
G0153	Speech-language pathology services	