Hearing Aids and Devices Including Wearable, Bone-Anchored, and Semi-Implantable (for Kansas Only)

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➲ Instructions for Use

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Related Policies

- Cochlear Implants (for Kansas Only)
- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Kansas Only)

Application

This Medical Policy only applies to the state of Kansas.

Coverage Rationale

Bone Anchored Hearing Aid

For medically necessity clinical coverage criteria for bone anchored hearing aids, refer to the Kansas Medical Assistance Program, Professional Audiology Fee-for-Service Provider Manual.

Wearable Air-Conduction Hearing Aids

For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Hearing Aids.

Click here to view the InterQual® criteria.

Semi or Fully Implantable Hearing Aids

For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Hearing Device, Middle Ear.

Click here to view the InterQual® criteria.

Bilateral or Unilateral Bone-Conduction Hearing Aids Utilizing a Headband or Adhesive (Without Osseointegration)

For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment Hearing Aids.

Click here to view the InterQual® criteria.

Additional Criteria

The following are unproven and not medically necessary for treating hearing loss due to insufficient evidence of efficacy:

- Intraoral bone conduction hearing aids

- Laser or light-based hearing aids
- Totally implanted middle ear hearing systems

Note: Equipment Upgrades
- A change in the member's medical condition and equipment needs requires the same criteria as a new request.
- Equipment upgrades are equivalent to a new service.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the services requested.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
Bone Anchored Hearing Aids (BAHA)	
69710	Implantation or replacement 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	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
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
Semi-Implantable Electromagnetic Hearing Aids (SEHA)	
69799	Unlisted procedure, middle ear
Totally Implantable Active Middle Ear Hearing Implant	
0951T	Totally implantable active middle ear hearing implant; initial placement, including mastoidectomy, placement of and attachment to sound processor
0952T	Totally implantable active middle ear hearing implant; revision or replacement, with mastoidectomy and replacement of sound processor
0953T	Totally implantable active middle ear hearing implant; revision or replacement, without mastoidectomy and replacement of sound processor

CPT Code	Description
Totally Implantable Active Middle Ear Hearing Implant	
0954T	Totally implantable active middle ear hearing implant; replacement of sound processor only, with attachment to existing transducers
0955T	Totally implantable active middle ear hearing implant; removal, including removal of sound processor and all implant components

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HCPCS Code	Description
Bone Anchored Hearing Aids (BAHA)	
L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
L8693	Auditory osseointegrated device abutment, any length, replacement only
L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each
Semi-Implantable Electromagnetic Hearing Aids (SEHA)	
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
V5095	Semi-implantable middle ear hearing prosthesis
Wearable Hearing Aids	
L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
V5030	Hearing aid, monaural, body worn, air conduction
V5040	Hearing aid, monaural, body worn, bone conduction
V5050	Hearing aid, monaural, in the ear
V5060	Hearing aid, monaural, behind the ear
V5070	Glasses, air conduction
V5080	Glasses, bone conduction
V5100	Hearing aid, bilateral, body worn
V5120	Binaural, body
V5130	Binaural, in the ear
V5140	Binaural, behind the ear
V5150	Binaural, glasses
V5171	Hearing aid, contralateral routing device, monaural, in the ear (ITE)
V5172	Hearing aid, contralateral routing device, monaural, in the canal (ITC)
V5181	Hearing aid, contralateral routing device, monaural, behind the ear (BTE)
V5190	Hearing aid, contralateral routing, monaural, glasses
V5211	Hearing aid, contralateral routing system, binaural, ITE/ITE
V5212	Hearing aid, contralateral routing system, binaural, ITE/ITC
V5213	Hearing aid, contralateral routing system, binaural, ITE/BTE
V5214	Hearing aid, contralateral routing system, binaural, ITC/ITC
V5215	Hearing aid, contralateral routing system, binaural, ITC/BTE
V5221	Hearing aid, contralateral routing system, binaural, BTE/BTE
V5230	Hearing aid, contralateral routing system, binaural, glasses
V5242	Hearing aid, analog, monaural, CIC (completely in the ear canal)
V5243	Hearing aid, analog, monaural, ITC (in the canal)
V5244	Hearing aid, digitally programmable analog, monaural, CIC
V5245	Hearing aid, digitally programmable, analog, monaural, ITC

HCPCS Code	Description
Wearable Hearing Aids	
V5246	Hearing aid, digitally programmable analog, monaural, ITE (in the ear)
V5247	Hearing aid, digitally programmable analog, monaural, BTE (behind the ear)
V5248	Hearing aid, analog, binaural, CIC
V5249	Hearing aid, analog, binaural, ITC
V5250	Hearing aid, digitally programmable analog, binaural, CIC
V5251	Hearing aid, digitally programmable analog, binaural, ITC
V5252	Hearing aid, digitally programmable, binaural, ITE
V5253	Hearing aid, digitally programmable, binaural, BTE
V5254	Hearing aid, digital, monaural, CIC
V5255	Hearing aid, digital, monaural, ITC
V5256	Hearing aid, digital, monaural, ITE
V5257	Hearing aid, digital, monaural, BTE
V5258	Hearing aid, digital, binaural, CIC
V5259	Hearing aid, digital, binaural, ITC
V5260	Hearing aid, digital, binaural, ITE
V5261	Hearing aid, digital, binaural, BTE
V5262	Hearing aid, disposable, any type, monaural
V5263	Hearing aid, disposable, any type, binaural
V5267	Hearing Aid or assistive listening device/supplies/accessories, not otherwise specified (**Note**: For plans that cover hearing aids, this code requires manual review to determine what the item is before a coverage determination can be made.)
V5298	Hearing aid, not otherwise classified

Description of Services

Intraoral Bone Conduction Hearing Aids

The SoundBite™ Hearing System is a non-surgical intraoral BCHA that was developed for individuals with single-sided deafness. It consists of a behind the ear (BTE) device (which houses the receiver, wireless transmitter, and microphone) and a removable, custom-fit oral retainer-like device. According to the manufacturer, the device allows sound to travel via the teeth, through the bones, to both cochleae, bypassing the middle and outer ear. As of January 1, 2015, Sonitus Medical, Inc. is no longer manufacturing the SoundBite Hearing System. There is no new information concerning production of this or a similar device.

Laser or Light-Based Hearing Aids

Laser or light-based Hearing Aids such as the Earlens Contact Hearing Device use light to transmit sound, unlike traditional Hearing Aids that simply amplify air-conducted sound. The Earlens Contact Hearing Device consists of two components: a light-based BTE sound processor and a removable, custom-made tympanic membrane transducer, which is nonsurgically placed deep in the ear canal. The BTE processor uses a microphone and a digital signal processor to pick up sound and convert it to infrared light. Light pulses are transmitted to the transducer and are converted into vibrations that are directly applied to the tympanic membrane and perceived as sound.

Totally Implanted Middle Ear Hearing Systems

Totally implantable middle ear hearing systems are also being evaluated in individuals with hearing loss. The Esteem prosthetic hearing restoration device (Envoy Medical Corporation) is totally implanted behind the outer ear and in the middle ear. Unlike other Hearing Aids, the Esteem device does not use a microphone or a speaker. Three implanted components comprise the system: a sound processor, a sensor, and a driver that converts electrical signals transmitted by the sound processor to the inner ear, where they are perceived as sound. The device is powered with a maintenance-free battery that may last up to nine years and requires no recharging. The Carina Fully Implantable Hearing Device (Cochlear, Ltd) is another totally implantable active middle ear device that was in development in the United States by

Otologics, LLC but did not receive FDA approval. In September of 2012, Cochlear, Ltd, an Australian based company, purchased the hearing related assets of Otologics, LLC.

Clinical Evidence

Intraoral Bone Conduction Hearing Aid

There is insufficient quality evidence to support the use of intraoral BCHAs to treat hearing loss. The quality of the studies was low due to small study populations, the short follow-up, and the lack of randomization and appropriate control groups.

In a prospective cases series, Gurgel et al. (2015) assessed the safety and efficacy of an intraoral bone conduction (IOBC) hearing prosthesis (SoundBite) after 12 months of use. At the end of 6 months and 12 months, participants were asked to complete the APHAB questionnaire and SSD questionnaire, in addition to audiometric testing. Overall, 81 participants aged 18 years or older with SSD completed the study. Hearing thresholds remained the same throughout the study. APHAB results showed a significant benefit in the categories of ease of communication, reverberation, background noise, and global score. The SSD questionnaire showed high satisfaction among participants, with 93.8% of participants being likely to recommend the IOBC. Dissatisfaction was highest regarding participants' ability to eat with the device, with only 55.6% being satisfied. No serious adverse events were reported during the study. The authors concluded that the IOBC is a safe and effective alternative to percutaneous osseointegrated hearing implants for individuals with SSD. Participant satisfaction and improved hearing benefit were observed after 1 year of using the device. According to the authors, the IOBC significantly benefited participants in the APHAB categories of ease of communication, reverberation, background noise, and overall global hearing score. The authors stated that the in-the-mouth transducer was the least-liked feature for some participants, particularly with regard to eating; however, the majority of participants were willing to tolerate the size of the device for the hearing benefit that was gained. The lack of a control group limits the validity of the results of this study. Author-reported study limitations include that (1) despite the APHAB being a well-validated way to assess the benefit of hearing prosthesis, the questionnaire responses were subjective and subject to bias, and (2) when comparisons were made between the 6- and 12-month APHAB results, 65 and 80 participants filled out the two questionnaires, respectively; the 6-month visit was not a required follow-up time, which explains the difference in participation, and the study results have some potential to be skewed because of the differential participation at the two time points, but the 6- and 12-month APHAB results were very similar, with no statistically significant differences. Additionally, selection bias is also possible in participants who were willing to participate in the study as well as providers who had incorporated the IOBC into their practice, and these participants and providers may feel more strongly for or against the device than more objective users. Lastly, more than 90% of participants responded that they preferred the device compared with no device and would likely recommend the device. This percentage may be artificially high because nine participants withdrew from the study, secondary to device-related problems, and did not complete the evaluation.

Moore and Popelka (2013) compared the effectiveness of two types of treatment for unilateral hearing loss: bone-anchored hearing instruments (BAHIs) and a dental device (SoundBite). Nine adult BAHI wearers with unilateral hearing loss were included in the study. Either a BAHI or SoundBite was worn for 30 days, and then the devices were swapped, and the second device was worn for 30 days. Measures included unaided and aided sound-field thresholds, sound localization, and perception of speech in babble. The APHAB questionnaire was administered for each trial period. Both devices gave benefits for localization after 30 days, but there was no difference between devices. Speech perception was better with both devices than with unaided listening when the target speech came from the poorer-hearing side or in front, and the interfering babble came from the better-hearing side. There was no consistent difference between devices. APHAB scores were better with SoundBite than with BAHIs. The authors concluded that speech perception and sound localization were similar with the two types of devices, but SoundBite led to lower aided thresholds and better APHAB scores than the BAHI. The significance of this study is limited by a small sample size, which could have limited the ability to detect clinically significant differences, and short follow-up period.

Laser or Light-Based Hearing Aids

There is insufficient quality evidence to support the use of laser or light-based hearing aids to treat hearing loss. The existing evidence is limited by lack of a concurrent control group.

Arbogast et al. (2019) evaluated the benefit of extended high-frequency amplification in a real-world use scenario, with a device that restores audibility for frequencies of up to 10 kHz. A total of 78 participants (149 ears) with mild to moderately severe SNHL completed one of two studies that were conducted across eight clinical sites. Participants were fitted with a light-driven contact hearing aid (the Earlens system) that directly drives the tympanic membrane, allowing extended high-frequency output and amplification, with minimal acoustic feedback. Participants wore the devices for an extended period. Prescribed vs adjusted output and gain, frequency-specific functional gain, and self-perceived benefit, which was assessed with the APHAB and a custom questionnaire, were documented. APHAB results revealed a significant

improvement in communication relative to unaided listening, averaging 28 to 32 percentage points for the background noise, reverberation, and ease of communication subscales. Relative to participants' own hearing aids, the subscales of ease of communication and aversiveness showed small but significant improvements for Earlens, ranging from 6 to 7 percentage points. For the custom satisfaction questionnaire, most participants rated the Earlens system as better than their own hearing aids in most situations. The investigators concluded that the results of the two studies show that the Earlens system can provide the gains and output levels prescribed by the Cambridge Method for Loudness Equalization 2 - High Frequency fitting method over the whole frequency range, up to 10 kHz, for individuals with a wide range of hearing losses. The limitation of the current two clinical trials is that they were not blinded, so the satisfaction measures may have been affected by placebo effects or biases. The lack of a concurrent comparison group is another weakness of this study.

In a single-arm, open-label, investigational-device clinical trial, Gantz et al. (2017) evaluated the safety and effectiveness of the light-driven contact hearing aid to support US Food and Drug Administration (FDA) clearance. The trial included 43 participants (86 ears) with mild-to-severe bilateral sensorineural hearing impairment. The intervention was the treatment of the hearing impairment using amplification that was provided by the Earlens Contact Hearing Aid for a duration of 120 days. The primary safety end point was a determination of "no change" (PTA4 < 10 dB) in residual unaided hearing at the 120-day measurement interval. The results for the 86 ears in the study determined a mean change of -0.40 dB in PTA4, indicating no change in residual hearing. There were no serious device- or procedure-related adverse events or unanticipated adverse events. Word recognition aided with the Earlens improved significantly over the unaided performance by 35% rationalized arcsine units, on average. The mean functional gain was 31 dB across 2 to 10 kHz. The average speech recognition threshold improvement over the unaided case for the Hearing in Noise Test was 0.75 dB and 3.14 dB for the omnidirectional and directional microphone modes, respectively. The authors concluded that the safety and effectiveness data supported a de novo 510(k) submission that received clearance from the FDA. According to the authors, future studies should perform careful comparisons between other devices and the contact hearing aid to establish whether the broad-spectrum amplification of the contact hearing aid provides additional benefits over those devices regarding sound quality and speech understanding.

Totally Implanted Middle Ear Hearing Systems

There is insufficient quality evidence that demonstrates the efficacy of totally implanted middle-ear hearing systems for treating hearing loss. The identified evidence described below is limited by the lack of a concurrent comparison group and conflicting findings, including identification of adverse events.

An ECRI clinical evidence assessment concluded that current evidence on the Esteem hearing implant is insufficient in both quantity and quality to support definitive conclusions about its comparative effectiveness versus conventional or other implanted hearing aids. Although some studies suggest Esteem may improve hearing in patients with sensorineural hearing loss (SNHL), serious adverse events including facial paralysis have been reported. One study also raises concerns about potential device-related long-term deterioration in age-related hearing loss. The available research includes fewer than 300 patients and is limited by small sample sizes, lack of independent controls, and retrospective designs. No studies have directly compared Esteem with other implanted devices, and no ongoing trials are currently underway (ECRI, 2025).

In a 2023 retrospective, single-arm, observational study, Peixoto et al. assessed the outcomes with a fully implantable active middle-ear device, the Cochlear Carina System. Fifteen patients and 16 ears underwent device implantation, and pre- and postoperative air conduction and bone conduction thresholds were evaluated. Functional gain, speech perception in silence and in noise, and localization abilities were also analyzed. The results showed no differences in air conduction and bone conduction thresholds prior to and post operation with the device turned off. This suggests that the surgery and device did not change middle-ear or cochlear functions. The results for device function showed no loss of external communication or device malfunction. Sound feedback was present to different degrees in all patients and required several appointments for fitting adjustments. Auditory outcomes showed a gain of 15 to 20 dB 1 year after implantations, with better gains seen in patients with mixed hearing loss than those with SNHL. Speech discrimination in silence showed a significant improvement of 29 dB in speech recognition threshold in patients with mixed hearing loss 1 year after surgery, with a progressive improvement seen in the first 6 months. This improvement was lower in patients with SNHL. Speech discrimination in noisy environments showed improvement, but this was not statistically significant. The authors concluded that a fully implantable active middle-ear device is a viable treatment option for individuals who cannot or do not wish to use traditional hearing aids. This study is limited by a small number of patients, short follow-up time, and lack of a comparison group.

Shohet et al. (2018) conducted a prospective, multicenter case series to provide long-term hearing outcome measures of a totally implantable hearing system (implant) and compare with the baseline unaided and baseline aided conditions as well as discuss relevant safety measures. Overall, 51 participants with mild to severe SNHL underwent implantation between 2008 and 2009 and were enrolled in this postmarket approval study in the setting of private and hospital-based

practices. In total, 49 of these participants completed the 5-year study, which included annual follow-ups. The primary effectiveness end points were SRT and WRSs at 50 dB. The secondary effectiveness end points were WRSs and APHAB scores. Adverse device effects and serious adverse device effects that were reported during the study period and a comparison of bone conduction scores were submitted as safety measures. The results showed that compared with the baseline aided condition, SRT scores were improved at every annual follow-up; WRSs at 50 dB were better in 49%, and the same in 41% at the 5-year follow-up. WRSs were improved by 17% at the 5-year follow-up, and APHAB scores were improved in most subscales at every annual follow-up. There were three serious adverse device effects in three participants and 15 adverse device effects in 11 participants. Bone conduction scores increased by 3.7 dB at the 5-year follow-up. The average battery life was 4.9 years. The authors concluded that the implant compared favorably with the participants' hearing aid throughout the 5-year period in all the areas measured and was found to be safe. Further research, with randomized controlled trials, is needed to validate these findings. The findings are limited by the lack of a comparison group.

Barbara et al. (2018) evaluated the long-term benefits of a totally implantable active middle-ear implant that has been used in a single implanting center for over 10 years. Overall, 41 individuals who underwent implantation with an Esteem active middle-ear implant during a 10-year period were evaluated on the auditory benefits, as derived from pure-tone and speech audiometry tests. The analysis included (1) a comparison with a conventional hearing aid but no concurrent comparison group, (2) the problematics related to the battery duration and surgical replacement, and (3) the complication rate. Over 80% of the implanted individuals maintained a satisfactory auditory gain over time, ranging from 10 to over 30 dB in respect to the unaided situation, as mean at 0.5, 1, 2, and 4 kHz. In more than 60% of them, an improvement was found at 4 and 8 kHz. Battery duration varied according to the severity of the hearing loss and to the daily use of the device. No major postoperative complications were recorded; explanation was necessary in five individuals, although none for device failure. The authors concluded that Esteem can be considered a reliable device for the rehabilitation of SNHL as an alternative to conventional hearing aids. The findings of this study need to be validated by well-designed, controlled studies that have larger sample sizes.

In a systematic review, Pulcherio et al. (2014) reviewed the outcomes with the fully implantable middle-ear devices, Carina and Esteem, for the treatment of hearing loss. Overall, 22 studies and two literature reviews in English, which directly addressed the results of Carina and Esteem, were included in the review. There was a total of 244 individuals, ranging from age 18 to 88 years. In total, 110 individuals were implanted with Carina and 134 with Esteem. Overall, 92 male individuals and 67 female individuals were registered. Five studies provided no information about the individuals' age or gender. From the data available, the follow-up ranged from 2 to 29.4 months. The comparison of the results about word recognition was difficult, as no standardization of measurement was available. The results were obtained from various sound intensities and different frequencies. The studies that were included in the review showed improvement of sound-field threshold from unaided to aided conditions with a fully implantable middle-ear device. However, there were conflicting results among the different studies regarding functional gain. Some of the studies had no statistical significance, and some studies reported a functional gain but with a limited benefit on frequencies above 3 kHz. According to the authors, the use of fully implantable middle-ear devices is promising for those dissatisfied with their current conventional air conduction hearing aids. The authors concluded that due to the relatively few publications that are available and the small sample sizes, one must be careful in extrapolating these results to a broader population. Additionally, none of these studies represented high levels of evidence (i.e., randomized controlled trials) or controlled studies.

Klein et al. (2012) conducted a systematic review to examine the safety and effectiveness of fully implantable middle-ear devices in the treatment of hearing loss. In total, 30 articles were selected for full review, of which seven on Esteem (n = 105) and 13 on Carina (n = 68) met the study's eligibility criteria. Because of heterogeneity across studies, a meta-analysis was not performed, and comparisons were made by structured review. Complication rates with Esteem were higher than with Carina. The most common adverse effects with Esteem were chorda tympani nerve damage and taste disturbance, occurring in 30% of individuals. Facial weakness was also reported in 8% of the individuals and was permanent in two individuals. Seven explants and five revision surgeries were reported with the Esteem device. Device failure was common with Carina, predominately related to charging difficulties. For both devices, clinically significant improvements in functional gain, speech reception, and speech recognition over the unaided condition were found. According to the authors, most of the studies that were included in the review were quasi-experimental pre-post comparisons of aided and unaided conditions. In addition, the studies had significant limitations, including the lack of a control group and no strict inclusion and exclusion criteria.

Clinical Practice Guidelines

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

The AAO-HNS considers active middle-ear implants as appropriate treatment for adults with moderate to severe hearing loss when performed by a qualified otolaryngologist-head and neck surgeon. Based on available literature demonstrating that clinically selected adults receive substantial benefit, implanting active middle-ear implants is accepted medical practice in those who benefit from amplification but are unable to benefit from the amplification that is provided by conventional hearing aids. Use of active middle-ear implants, which have been FDA-approved for these indications, should adhere to the restrictions and guidelines specified by the appropriate governing agency such as the FDA in the United States and other similar regulatory agencies in countries other than the United States (AAO-HNS, Active Middle Ear Implants Position Statement 2016, reviewed 2025).

The AAO-HNS considers bone conduction hearing devices as appropriate, and in some cases preferred, for the treatment of conductive and mixed hearing loss. Bone conduction hearing devices may also be indicated in select patients with SSD. Bone conduction hearing devices include semi-implantable BCDs that use either a percutaneous or transcutaneous attachment as well as bone conduction oral appliances and scalp-worn devices. The recommendation for a bone conduction hearing device should be determined by a qualified otolaryngology-head and neck surgeon. These devices are approved by the FDA for these indications, and their use should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the FDA in the United States and the respective regulatory agencies in countries other than the United States (AAO-HNS, Bone Conduction Hearing Devices Position Statement 2016; reviewed 2025).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Semi-Implantable Electromagnetic Hearing Aid

Two semi-implantable, electromagnetic, direct-drive, middle-ear hearing devices have received FDA approval.

Vibrant received FDA approval on August 31, 2000. According to the FDA, Vibrant Soundbridge is used for providing a useful level of sound perception to individuals via mechanical stimulation of the ossicles.

According to the professional labeling information on the FDA website, the selection criteria for Vibrant Soundbridge include the following:

- Adults aged 18 years or older
- Audiological results consistent with moderate to severe sensorineural hearing loss
- Pure-tone air conduction threshold levels within the following ranges:
  - 500 Hz: 30 to 65 dB
  - 1,000 Hz: 40 to 75 dB
  - 1,500 Hz: 45 to 80 dB
  - 2,000 Hz: 45 to 80 dB
  - 3,000 Hz: 50 to 85 dB
  - 4,000 Hz: 50 to 85 dB
- Word Recognition Score of 50% or better using recorded material
- Normal middle-ear anatomy
- Psychologically and motivationally suitable, with realistic expectations of the benefits and limitations of the device

Refer to the following website for more information:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p990052. (Accessed October 16, 2025)

MAXUM Hearing Implant® was approved by the FDA on September 7, 2001. This device was manufactured initially under the name Soundtec Direct System by Ototronix and is currently manufactured under the name MAXUM Hearing Implant. According to the professional labeling information on the FDA website, the selection criteria for MAXUM Hearing Implant include the following:

- Adults aged 18 years or older
- Audiological results consistent with moderate to severe sensorineural hearing loss
- Patients with a desire for an alternative to an acoustic hearing device
- Patients should have experience with appropriately fit hearing aids

Refer to the following website for more information:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P010023. (Accessed October 16, 2025)

Bone-Anchored Hearing Aids

Fully Implantable Bone-Anchored Hearing Aids

In 1995, the FDA granted clearance to Nobelpharma USA to market the Branemark Bone-Anchored Hearing Aid (BAHA) System. Note: Since 1995, the device was acquired by Entific Medical Systems, and then in 2005, it was acquired by Cochlear Ltd and is now marketed as the Cochlear Baha System®. The device is indicated for adult patients with malformations of the external ear, a chronically draining ear, a pure-tone threshold hearing loss of ≥ 45 dB, and/or an inability or unwillingness to use an air conduction hearing aid. In 1999, this clearance was extended for use in children 5 years of age or older. Refer to the following website for more information:
http://www.accessdata.fda.gov/cdrh_docs/pdf/K984162.pdf. (Accessed October 16, 2025)

The indications for the BAHA System have broadened since the initial FDA clearance. In 2001, the BAHA System was cleared for bilateral implantation. For bilateral implantation of bone-anchored hearing aids, patients must have moderate to severe, bilateral, symmetrical conductive hearing loss (defined as a less than 10-dB difference in average or less than 15 dB in bone conduction thresholds at 500, 1,000, 2,000, and 4,000 Hz) or mixed hearing loss, with average bone conduction thresholds better than 45-dB hearing loss.

In 2002, the BAHA System was cleared for single-sided deafness (SSD) or unilateral sensorineural hearing loss. According to the FDA, the use of the BAHA hearing aid for SSD is intended to improve speech recognition. The SSD indication for the BAHA hearing aid is intended for patients with unilateral sensorineural deafness in one ear, while the other ear has normal hearing. Normal hearing is defined as a pure-tone average (PTA) air conduction threshold that is equal to or better than 20 dB, measured at 0.5, 1, 2, and 3 kHz. BAHA for SSD is also indicated for patients who are indicated for an air conduction Contralateral Routing of Signals (CROS) but who, for some reason, cannot or will not use an air conduction CROS. Refer to the following website for more information:
http://www.accessdata.fda.gov/cdrh_docs/pdf2/k021837.pdf. (Accessed October 16, 2025)

BAHA System models include the following:

- BAHA BP100 (2009). Refer to the following website for more information:
  - http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090720.pdf
- BAHA Cordelle II. Refer to the following website for more information:
  - http://www.accessdata.fda.gov/cdrh_docs/pdf8/K080363.pdf
  - https://www.accessdata.fda.gov/cdrh_docs/pdf/K992872.pdf
- BAHA Intenso (2008). Refer to the following website for more information:
  - http://www.accessdata.fda.gov/cdrh_docs/pdf8/K081606.pdf
- BAHA Divino (2004). Refer to the following website for more information:
  - http://www.accessdata.fda.gov/cdrh_docs/pdf4/K042017.pdf
- BAHA auditory osseointegrated implant system using model B31300 implant and model BA300 abutment (2010). Refer to the following website for more information:
  - http://www.accessdata.fda.gov/cdrh_docs/pdf10/K100360.pdf

(Accessed September 23, 2024)

In November 2008, the OBC Bone Anchored Hearing Aid System (Oticon Medical) was cleared by the FDA for marketing through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices. Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf8/k082108.pdf.
(Accessed October 16, 2025)

In September 2012, the Ponto Bone Anchored Hearing System (Oticon Medical) was cleared by the FDA for marketing through the 510(k) process. Refer to the following website for more information:
https://www.accessdata.fda.gov/cdrh_docs/pdf12/K121228.pdf. (Accessed October16, 2025)

In August 2021, the Ponto 5 Mini (Oticon Medical) was cleared by the FDA for marketing through the 510(k) process. Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211640.pdf.
(Accessed October 16, 2025)

Other bone-anchored hearing aid devices have also been cleared by the FDA. Refer to the following website for more information (use product code LXB or MAH): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed October 16, 2025)

Partially Implantable Bone-Anchored Hearing Aids or Devices

The partially implanted Otomag Alpha 1 (M) Bone Conduction Hearing System (Sophono, Inc.) received FDA clearance in May 2011 as a bone conduction hearing aid. The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations) or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing loss, who can still benefit from amplification of sound. The PTA bone conduction threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz)
- Bilateral fitting is applicable for most patients who have symmetrically conduction or mixed hearing loss. The difference between the left and right sides' bone conduction thresholds should be less than 10 dB on average, measured at 0.5, 1, 2, and 4 kHz or less than 15 dB at individual frequencies
- Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who, for some reason, will not or cannot use an air conduction CROS. The PTA air conduction threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2, and 3 kHz)

Refer to the following websites for more information about FDA clearances for Sophono hearing systems:

- http://www.accessdata.fda.gov/cdrh_docs/pdf10/K102199.pdf
- http://www.accessdata.fda.gov/cdrh_docs/pdf15/K153391.pdf
- https://www.accessdata.fda.gov/cdrh_docs/pdf13/K132189.pdf
- https://www.accessdata.fda.gov/cdrh_docs/pdf12/K123962.pdf

(Accessed October 16, 2025)

The Cochlear Baha Attract System (Cochlear Ltd) received FDA clearance on November 7, 2013. The Cochlear Baha Attract is intended for the following patients and indications for use:

- Patients aged 5 years or older
- Patients who have conductive or mixed hearing loss and can still benefit from sound amplification. The PTA bone conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB3 HL for use with the BP1 00 sound processor and 55 dB HL for use with the BP1IO0 sound processor
- Bilateral fitting is intended for patients who meet the above criterion in both ears, with bilaterally symmetric, moderate to severe conductive or mixed hearing loss
- Symmetrical bone-conductive thresholds are defined as less than a 10-dB3 average difference between ears (measured at 0.5, 1, 2, and 3 kHz) or less than a 15-dB difference at individual frequencies
- Patients who have unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e., SSD). Normal hearing is defined as a PTA air conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 d13 HL
- Baha for SSD is also indicated for any patient who is indicated for an air conduction CROS (AC CR08) hearing aid but who, for some reason, cannot or will not use an AC CR08

Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf13/K131240.pdf. (Accessed October 16, 2025).

The BONEBRIDGE (MED-EL), a transcutaneous bone conduction hearing device, was cleared by the FDA via the de novo regulatory pathway on July 20, 2018. The FDA subsequently granted 510(k) marketing clearance (K183373) in March 2019. The BONEBRIDGE bone conduction hearing implant system is intended for the following patients and indications:

- Patients 12 years of age or older
- Patients who have conductive or mixed hearing loss and still can benefit from sound amplification. The PTA bone conduction threshold (measured at 0.5,1, 2, and 3 kHz) should be better than or equal to 45 dB HL
- Bilateral fitting of the BONEBRIDGE is intended for patients who have symmetrically conductive or mixed hearing loss. The difference between the left and right sides' bone conduction thresholds should be less than 10 dB, on average, measured at 0.5, 1, 2, and 3 kHz or less than 15 dB at individual frequencies
- Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., SSD). The PTA air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz)
- The BONEBRIDGE for SSD is also indicated for any patient who is indicated for an air conduction CROS hearing aid but who, for some reason, cannot or will not use an air conduction CROS
- Before receiving the device, it is recommended that an individual have experience with appropriately fit air conduction or bone conduction hearing aids

Refer to the following websites for more information:
- https://www.accessdata.fda.gov/cdrh_docs/pdf17/DEN170009.pdf
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K183373

(Accessed October 16, 2025)

In 2019, Cochlear's Osia System and Cochlear's Osia 2 System (Cochlear Ltd.) were FDA 510(k) approved as Class II devices (K190589, K191921) as active implantable bone conduction hearing systems. Both the Osia System and the Osia 2 System are made up of several components. The Osia Implant (OSI100) consists of a receiver/stimulator and an actuator (vibrator) which is surgically implanted on the skull bone. The Osia 2 Implant (OSI200) consists of a receiver/coil and an actuator/stimulator (vibrator) which is also surgically implanted on the skull bone. The external component of the Osia System is a sound processor, which is worn off the ear, that picks up the sound from the environment and sends, after processing, the information to the implant via a transcutaneous inductive link. This link is also referred to as a radiofrequency link. Each Osia System and Osia 2 System is configured to meet an individual's hearing needs, using dedicated fitting software. The Osia System and Osia 2 System use a Piezo Power™ transducer that sits within the OSI100/OSI200 Implant. The transducer is positioned under the skin to send sound to the cochlea. The OSI100/OSI200 Implant is positioned on top of the bone, connected to the BI300 Implant (in the same manner as that used in Baha Connect/Attract), and osseointegrated into the bone; this gives an important single point of transmission for sound. The system has a fitting range of 55 dB. sensorineural hearing loss. Per the FDA, both the Osia System and the Osia 2 System are intended for the following patients and indications:
- Patients 12 years of age or older
- Patients who have conductive or mixed hearing loss and still can benefit from sound amplification. The PTA bone conduction threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dB HL
- Bilateral fitting of either the Osia System or the Osia 2 System is intended for patients who have symmetrically conductive or mixed hearing loss. The difference between the left and right sides' bone conduction thresholds should be less than 10 dB, on average, measured at 0.5, 1, 2, and 3 kHz or less than 15 dB at individual frequencies
- Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., SSD). The PTA air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz)
- The Osia System and the Osia 2 System for SSD are also indicated for any patient who is indicated for an air conduction CROS hearing aid but who, for some reason, cannot or will not use an air conduction CROS. Page 9 of 23 Medical Coverage Policy: 0093
- Prior to receiving the device, it is recommended that an individual has experience with appropriately fitted air conduction or bone conduction hearing aids

The FDA subsequently granted 510(k) marketing clearance for the Class II devices (K190589, K191921) for the Osia in November 2019. Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191921.pdf. (Accessed October16, 2025)

Nonimplantable Bone Conduction Hearing Aids

In 2025, the FDA cleared the Cochlear Baha 7 Sound Processor is intended for the following individuals and indications for use:
- Patients of any age may use the Baha SoundBand, Baha Softband (or headband), or Baha SoundArc
- Patients aged 5 and older may use the Baha auditory osseointegrated implant system
- Patients with conductive or mixed hearing loss who can still benefit from sound amplification.The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dB HL
- Bilateral fitting is intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies
- Patients with unilateral sensorineural deafness in one ear and normal hearing in the other ear (i.e., single-sided deafness or SSD). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL.

Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf25/K250215.pdf. (Accessed October, 16, 2025)

In 2000, the FDA cleared the BAHA Headband. The BAHA with headband is intended for patients with moderate to severe conductive hearing losses. The BAHA with headband may be particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms. Refer to the following

website for more information:
http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K002913. (Accessed October16, 2025)

In 2009, the FDA cleared the Cochlear Baha BP100 sound processor that is intended for use with the Baha auditory osseointegrated implant (for children aged 5 years or older or adults) or with the Baha Headband or Baha Softband (no age limitations) for the following patients and indications:

- Patients who have conductive or mixed hearing loss and can still benefit from sound amplification. The PTA bone conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB HL
- Bilateral fitting of the BP100 is intended for patients who meet the above criterion in both ears, with bilaterally symmetric, moderate to severe conductive or mixed hearing loss. Symmetrical bone conduction thresholds are defined as less than a 10-dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz) or less than a 15-dB difference at individual frequencies
- Patients with unilateral sensorineural deafness in one ear, with normal hearing in the other ear (i.e., SSD). Normal hearing is defined as a PTA air conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to .20 dB HL
- Baha for SSD is also indicated for any patient who is indicated for an air conduction CROS hearing aid but who, for some reason, cannot or will not use an air conduction CROS

Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090720.pdf. (Accessed October16, 2025)

The Baha SoundArc received FDA clearance on June 7, 2017. The Baha SoundArc is intended for patients who cannot or choose not to have an implant for the following indications for use:

- Patients of any age who have conductive or mixed hearing loss and can still benefit from sound amplification. The PTA bone conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB HL for use with the BP100, Baha 4, and Baha 5 sound processors; 55 dB HL for use with the BP110 Power and Baha 5 Power sound processors; and better than or equal to 65 dB HL for use with the Cordelle II and Baha 5 SuperPower sound processors
- Bilateral fitting is intended for patients who meet the above criterion in both ears, with bilaterally symmetric, moderate to severe conductive or mixed hearing loss. Symmetrical bone-conductive thresholds are defined as less than a 10-dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz) or less than a 15-dB difference at individual frequencies
- Patients with unilateral sensorineural deafness in one ear, with normal hearing in the other ear (i.e., SSD). Normal hearing is defined as a PTA air conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL
- Baha for SSD is also indicated for any patient who is indicated for an air conduction CROS hearing aid but who, for some reason, cannot or will not use an air conduction CROS

Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171088.pdf. (Accessed October16, 2025)

Baha sound processors can be used with the Baha Softband. With this application, there is no implantation surgery. The sound processor is attached to the head using a hard or soft headband. The amplified sound is transmitted transcutaneously to the cochlea via the bones of the skull. In 2002, the Baha Softband was cleared for marketing by the FDA for use in children younger than 5 years.

In May 2010, the FDA cleared the Otomag Alpha 1(S) Sound Processor for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The PTA bone conduction threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz)
- Bilateral fitting is applicable for most patients who have symmetrically conductive or mixed hearing loss. The difference between the left and right sides' bone conduction thresholds should be less than 10 dB, on average, measured at 0.5, 1, 2, and 4 kHz or less than 15 dB at individual frequencies
- Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who, for some reason, will not or cannot use an air conduction CROS. The PTA air conduction threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2, and 3 kHz)

Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf10/K100193.pdf. (Accessed October 16, 2025)

In April 2018, the ADHEAR system was cleared by the FDA for marketing through the 510K process. The ADHEAR system is intended to treat patients of all ages with conductive hearing loss or SSD via bone conduction. The ADHEAR system is a noninvasive bone conduction hearing device that is retained on the patient's head with an elastic headband or an adhesive adapter that is placed behind the auricle.
Indications:

- Unilateral or bilateral conductive hearing loss, either chronic or temporary
- The PTA bone conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 25 dB HL
- SSD (i.e., unilateral profound sensorineural deafness), with normal hearing on the contralateral side
- Normal hearing is defined as a PTA air conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL

Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172460.pdf. (Accessed October 16, 2025)

Other nonimplantable bone-anchored hearing aid devices have also been cleared by the FDA. Refer to the following website for more information (use product code LXB): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October15, 2025)

Totally Implanted Middle-Ear Hearing System

The Esteem prosthetic hearing restoration device has been approved by the FDA. Refer to the following websites for more information:

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P090018
- https://www.accessdata.fda.gov/cdrh_docs/pdf9/p090018c.pdf
- https://www.accessdata.fda.gov/cdrh_docs/pdf9/p090018b.pdf

(Accessed October 2, 2024)

Intraoral Bone Conduction Hearing Aid

Currently, there are no FDA approved intraoral bone conduction hearing aids, The SoundBite Hearing System received FDA clearance in 2011. In 2015, Sonitus Medical filed for bankruptcy, and manufacturing of this device ceased.

Laser or Light-Based Contact Hearing Aid

In April 2016, the FDA cleared the Earlens Contact Hearing Device via the 501(k) regulatory pathway. It is indicated for individuals aged 18 years or older with a mild to severe sensorineural hearing impairment who can benefit from amplification. The device can provide the full spectrum of amplification that includes 125 Hz to 10,000 Hz. Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf15/K153634.pdf. (Accessed October16, 2025)

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Policy History/Revision Information

Date	Summary of Changes

06/01/2026	**Medical Records Documentation Used for Reviews**
	• Added language to indicate:
	  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service
	  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested
	  ○ The patient's medical record must contain documentation that fully supports the medical necessity for the requested services
	  ○ This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures
	  ○ Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request
	Applicable Codes
	• Removed list of applicable CPT/HCPCS codes for **Fitting and Testing of Hearing Aids**: 92590, 92591, 92592, 92593, 92594, 92595, 92595, S0618, V5010, V5011, V5014, V5020, V5264, V5265, and V5275
	Supporting Information
	• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
	• Archived previous policy version CS052KS.02

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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