

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

Policy Number: CSNCT0396.10

Effective Date: June 1, 2026

[➔ Instructions for Use](#)

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Related Policies
<ul style="list-style-type: none"> • Cochlear Implants (for North Carolina Only) • Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for North Carolina Only)

Application

This Medical Policy only applies to the state of North Carolina.

Coverage Rationale

Hearing Aids

For medical necessity clinical coverage criteria, refer to the [North Carolina Medicaid \(Division of Health Benefits\) Clinical Coverage Policy, Hearing Aid Services: 7, Hearing Aid Services](#).

Implantable Bone Conduction Hearing Aids (BAHA)

For medical necessity clinical coverage criteria, refer to the [North Carolina Medicaid \(Division of Health Benefits\) Clinical Coverage Policy, Physician: 1A-36, Implantable Bone Conduction Hearing Aids \(BAHA\)](#).

External Parts Replacement and Repairs

For medical necessity clinical coverage criteria, refer to the [North Carolina Medicaid \(Division of Health Benefits\) Clinical Coverage Policy, Auditory Implant External Parts: 13B, Soft Band and Implantable Bone Conduction Hearing Aid External Parts Replacement and Repair](#).

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
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

CPT® is a registered trademark of the American Medical Association

HCPCS Code	Description
Bone Anchored Hearing Aids (BAHA)	
*L8690	Auditory osseointegrated device, includes all internal and external components
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	
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each

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

HCPCS Code	Description
Wearable Hearing Aids	
*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

Codes labeled with an asterisk (*) are not on the State of North Carolina Medicaid Fee Schedule and therefore may not be covered by the State of North Carolina Medicaid Program.

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
 - 1000 Hz: 40 to 75 dB
 - 1500 Hz: 45 to 80 dB
 - 2000 Hz: 45 to 80 dB
 - 3000 Hz: 50 to 85 dB
 - 4000 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)

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UnitedHealthcare Community Plan Medical Policy

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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, 1000, 2000, and 4000 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 October 16, 2025)

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 October 16, 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 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 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 and 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 dB 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 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 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 dB 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 a 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 October 16, 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. 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 October 16, 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 a 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 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 October 16, 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 October 16, 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 transcutaneous 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 100dB 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 H-IL (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 October 16, 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 16, 2025)

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 October 16, 2025)

References

North Carolina Medicaid, Division of Health Benefits, Clinical Coverage Policies, Hearing Aids Services, No: 7. <https://medicaid.ncdhhs.gov/media/12383/download?attachment>. Accessed March 2, 2026.

North Carolina Medicaid, Division of Health Benefits, Clinical Coverage Policies, Implantable Bone Conduction Hearing Aids (BAHA) No: 1A-36. <https://medicaid.ncdhhs.gov/1a-36-implantable-bone-conduction-hearing-aids-baha/download?attachment>. Accessed March 2, 2026.

North Carolina Medicaid, Division of Health Benefits, Clinical Coverage Policies, Soft Band and Implantable Bone Conduction Hearing Aids External Parts Replacement and Repair, No: 13B. <https://medicaid.ncdhhs.gov/13b-soft-band-and-implantable-bone-conduction-hearing-aid-external-parts-replacement-and-repair/download?attachment>. Accessed March 2, 2026.

Policy History/Revision Information

Date	Summary of Changes
06/01/2026	<p data-bbox="337 201 1040 233">Medical Records Documentation Used for Reviews</p> <ul data-bbox="337 233 1495 569" style="list-style-type: none">● Added language to indicate:<ul style="list-style-type: none">○ 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 <p data-bbox="337 569 581 600">Applicable Codes</p> <ul data-bbox="337 600 1458 695" style="list-style-type: none">● Removed list of applicable CPT/HCPCS codes for Fitting and Testing of Hearing Aids: 92590, 92591, 92592, 92593, 92594, 92595, S0618, V5010, V5011, V5014, V5020, V5264, V5265, and V5275 <p data-bbox="337 695 662 726">Supporting Information</p> <ul data-bbox="337 726 1084 791" style="list-style-type: none">● Updated <i>FDA</i> section to reflect the most current information● Archived previous policy version CSNCT0396.09

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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual[®] criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.