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

Policy Number: CS052IN.02
Effective Date: August 1, 2021

Instructions for Use

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Related Policies

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

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

For medical necessity clinical coverage criteria, refer to the Indiana Hearing Services Provider Reference Module.

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
Fitting and Testing of Hearing Aids	
92590	Hearing aid examination and selection; monaural
92591	Hearing aid examination and selection; binaural
92592	Hearing aid check; monaural
92593	Hearing aid check; binaural
92594	Electroacoustic evaluation for hearing aid; monaural
92595	Electroacoustic evaluation for hearing aid; binaural
Semi-Implantable Electromagnetic Hearing Aids (SEHE)	
69799	Unlisted procedure, middle ear

CPT Code	Description
Bone Anchored Hearing Aids (BAHA)	
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy

HCPCS Code	Description
Fitting and Testing of Hearing Aids	
S0618	Audiometry for hearing aid evaluation to determine the level and degree of hearing loss
V5010	Assessment for hearing aid
V5011	Fitting/orientation/checking of hearing aid
V5014	Repair/modification of a hearing aid
V5020	Conformity Evaluation
V5264	Ear mold/insert, not disposable, any type
V5265	Ear mold/insert, disposable, any type
V5275	Ear impression, each
Semi-Implantable Electromagnetic Hearing Aids (SEHE)	
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
V5095	Semi-implantable middle ear hearing prosthesis
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
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

HCPCS Code	Description
Wearable Hearing Aids	
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
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

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 utilized 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 or older
- Audiologic results consistent with moderate to severe sensorineural hearing loss
- Pure tone air conduction threshold levels within the following ranges:
  - 500 Hz: 30-65 dB; 1000 Hz: 40-75 dB; 1500 Hz: 45-80 dB; 2000 Hz: 45-80 dB; 3000 Hz: 50-85 dB; 4000 Hz: 50-85 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 August 21, 2019)

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 or older
- Audiologic 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_template.cfm?id=p010023s013.
(Accessed August 21, 2019)

Bone-Anchored Hearing Aids

Fully Implantable Bone Anchored Hearing Aids

In 1995, the FDA granted clearance to Nobelpharm 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 Corp. The device is indicated for adult patients with malformations of the external ear, chronically draining ear, a pure tone threshold hearing loss of ≥ 45 decibels (dB), and/or 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 August 21, 2019)

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 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 BAHA hearing aid for SSD is intended to improve speech recognition. The SSD indication for BAHA hearing

aid is intended for patients who suffer from unilateral sensorineural deafness on one ear while the other ear has normal hearing. Normal hearing is defined as PTA AC threshold equal to or better than 20dB measured at 0.5, 1, 2 and 3 kHz. BAHA for SSD is also indicated for patients who are indicated for an AC Contra-lateral Routing of Signals (CROS), but who for some reason cannot, or will not use an AC CROS. Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf2/k021837.pdf. (Accessed August 21, 2019)

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 websites 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 August 21, 2019)

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 August 21, 2019)

In September 2012, the Pronto 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 14, 2019)

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 August 21, 2019)

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 Sofiband (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 pure tone average (PTA) bone conduction (BC) 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 having a symmetrically conduction or mixed hearing loss. The difference between the left and right sides' BC 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 a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) 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/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K132189
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K123962

(Accessed August 21, 2019)

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

- Patients aged 5 and older
- Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3kHz) 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 15dB difference at individual frequencies.
- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e., Single-sided deafness: 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 20d13 HL.
- Baha for SSD is also indicated for any patient who is indicated for an air conduction contralateral routing of signals (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 August 21, 2019)

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 de novo process provides a pathway to classify low- to moderate-risk devices for which general controls or general and special controls provide reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. 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 a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) 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 having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC 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., single-sided deafness [SSD]). The pure tone average 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 contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.
- Before receiving the device, it is recommended that an individual have experience with appropriately fit air conduction or bone conduction hearing aids.

The FDA subsequently granted 510(k) marketing clearance (K183373) for the Bonebridge in March 2019. 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 August 16, 2019)

Non-Implantable Bone-Anchored Hearing Aids

In 2000, the FDA cleared the BAHA headband. The BAHA with headband is intended for patients who suffer from 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 August 21, 2019)

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 and 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 pure tone average 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 who suffer from unilateral sensorineural deafness in one ear with 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.
- Baha for SSD is also indicated for any patient who is indicated for an air conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090720.pdf. (Accessed August 21, 2019)

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 pure tone average (PTA) bone conduction (BC) 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 having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10OdB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear who for some reason will not or cannot use an AC CR05. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB H-IL (measured at 0.5, 1, 2 and 3 kl-z).

Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf10/K100193.pdf. (Accessed August 21, 2019)

Other non-implantable 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 August 21, 2019)

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 September 11, 2019)

Intraoral Bone Conduction Hearing Aid

The SoundBite Hearing System received FDA clearance in 2011. Refer to the following websites for more information:

- http://www.accessdata.fda.gov/cdrh_docs/pdf10/K100649.pdf
- http://www.accessdata.fda.gov/cdrh_docs/pdf11/K110831.pdf

(Accessed September 11, 2019)

Laser or Light Based Contact Hearing Aid

The FDA has cleared the Earlens Contact Hearing Device via the de novo regulatory pathway. Refer to the following websites for more information:

- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?ID=DEN150002
- http://www.accessdata.fda.gov/cdrh_docs/pdf15/DEN150002.pdf

(Accessed September 11, 2019)

Policy History/Revision Information

Date	Summary of Changes

08/01/2021	**Applicable Codes**
	• Changed service type classification for HCPCS code:
	  ○ L8692 from “Bone Anchored Hearing Aid (BAHA)” to “Wearable Hearing Aid”
	  ○ L8694 from “Wearable Hearing Aid” to “Bone Anchored Hearing Aid (BAHA)”
	Supporting Information
	• Archived previous policy version CS052IN.01

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, please 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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