Implantable and Non-Implantable Hearing Devices

Humana®

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Medical Coverage Policy

Table of Contents

Related Medical/Pharmacy Coverage Policies

None

Description

Hearing aids are the most commonly known devices for assisting an individual with hearing loss. These are external devices worn either just inside the ear or looped over the ear and can be removed by the wearer. Other types of devices (implantable and semi-implantable) have been developed to treat varying types of hearing loss. Hearing loss is classified by the severity or degree of hearing loss and can be unilateral or bilateral.

There are three main types of hearing loss including:

- **Conductive** – Caused by disruptions in sound transmission from getting through the outer ear or middle ear to the cochlea, the hollow tube coiled in the shape of a snail's shell, that changes sound into nerve messages and sends them to the brain.

- **Sensorineural hearing loss** – Caused by disruptions in sound transmission from the cochlea to the brain. This type of hearing loss occurs when there is an issue with the way the inner ear or hearing nerve works.

- **Mixed hearing loss** – Caused by a mix of both conductive and sensorineural hearing loss.

Auditory Brainstem Implant

An auditory brainstem implant is a specialized implantable hearing device used in an individual who has had surgical removal of auditory nerve tumors and is totally deaf as a result. Similar to a cochlear implant, it consists of several components: a microphone, which picks up sound and transmits an electrical signal to the speech processor; the speech processor converts the signal to digital impulses, which are sent to a transmitter coil worn behind the ear and directly over the implant that is embedded in the skull.

The implant relays the signals to an electrode placed on the brainstem near the severed auditory nerve; the signals stimulate the brainstem and can be interpreted by the brain in a manner similar to the interpretation of signals normally received from the ear. After surgical placement, the implant must be programmed and tested. The individual must undergo a period of training to recognize sounds and communicate with the device. Currently, the only US Food & Drug Administration (FDA) approved auditory brainstem implant is the **Nucleus Profile Plus Auditory Brainstem Implant**.

Bone Anchored/Bone Conduction Hearing Aids

A **percutaneous bone anchored hearing aid** (pBAHA), also known as an osseointegrated mastoid implant, is a type of implantable hearing device based on bone conduction of sound. Certain individuals, typically those with conductive or mixed hearing loss, who are unable to utilize a conventional hearing aid may benefit from this device since it transmits sound directly through the skull. A titanium post is surgically embedded into the skull with a small section, called an abutment, exposed outside of the skin. A sound processor sits on the abutment and transmits sound vibrations via the titanium post. The vibrations to the skull and inner ear stimulate the nerve fibers of the inner ear, which enables hearing. Examples of bone anchored hearing aids include, but may not be limited to, **Baha Connect System** and **Ponto Bone Anchored Hearing System**, both of which have several different sound processor models.

A **transcutaneous bone anchored hearing aid** (tBAHA), also known as a partially implantable hearing aid, utilizes a magnetic abutment under the skin which is surgically implanted in an outpatient setting. These systems use the magnetic connection to join the sound processor and implant. This device creates an electromagnetic field that vibrates and stimulates the ossicles, sending signals to the cochlea to improve hearing acuity. Examples of transcutaneous bone anchored hearing aids include, but may not be limited to, **Alpha 2 MPO ePlus**, **Baha Attract System, BONEBRIDGE** and **Osia System**.

Cochlear Implant

A cochlear implant is an electronic device that can provide improved speech and hearing communication abilities for an individual who has severe-to-profound, sensorineural hearing loss (SNHL) in both ears and who still has difficulty hearing despite appropriately fitting conventional hearing aids. The implant is surgically placed under the skin, behind the ear. It generally consists of four parts: a microphone, which picks up sound from the environment; a speech processor, which is worn externally or carried and arranges the sound transmitted by the microphone; a receiver/stimulator that receives signals from the speech

processor and converts them into electrical impulses; and an electrode, which collects the impulses from the stimulator and sends them to the brain.

Although it cannot restore normal hearing, the cochlear implant enables an individual with profound or total deafness to hear sound, including speech, by stimulating the auditory nerve in the inner ear. Following implantation, the device must be programmed, calibrated and the individual trained to use it. The effectiveness of the implant depends heavily on postoperative rehabilitation that is necessary for the individual to learn to communicate using the device. Examples of cochlear implants include, but may not be limited to, **HiRes Ultra/HiRes Ultra 3D Cochlear Implant, Neuro Cochlear Implant System, Nucleus Profile Plus Cochlear Implant System**, and **Synchrony 2 Cochlear Implant**.

Assistive listening devices purportedly enhance the function of a cochlear implant or hearing aid by helping to separate desired sounds from background noise. These devices generally consist of a microphone to collect sound, a transmitter to send the signal across a distance, a receiver to intercept the signal and any one of several different listening attachments to send the sound from the receiver to the individual's ear, hearing aid or cochlear implant. **(Refer to Coverage Limitations section)**

Hybrid cochlear implants purportedly provide both electric (cochlear implant portion) and acoustic (hearing aid portion) stimulation to individuals with severe-to-profound hearing loss that may still hear low frequency sounds. The hybrid implant electrodes are shorter and thinner than cochlear implant electrodes and are implanted only halfway in an effort to preserve the area responsible for low frequency sounds.[33] An example of a hybrid cochlear implant includes, but may not be limited to, the **Nucleus Hybrid Implant System**. **(Refer to Coverage Limitations section)**

Fully Implantable Middle Ear Hearing System

Fully implantable middle ear hearing systems, in which all components are surgically positioned in the middle ear, are purported to be an alternative to the traditional over the ear hearing aid. The device uses the eardrum like a microphone and there is a sensor placed on the incus. The mechanical motion produced at the incus is then converted into an electrical signal and is sent to the processor which amplifies and filters that signal. Once converted to a vibratory signal it is then transmitted into the inner ear where it is perceived as sound.[50] An example of a fully implantable hearing system includes, but may not be limited to, the **Esteem Implant**. **(Refer to Coverage Limitations section)**

Non-Implantable Hearing Devices

Nonimplanted bone conduction devices are intended for children and some adults to use prior to bone anchored hearing aid placement. These include bands or adhesive patches that can be worn over the mastoid bone which purportedly send sound waves through the bone and into the inner ear. Examples of these devices include, but may not be limited to, **Baha Softband, Baha SoundArc, ADHEAR** and **Ponto Softband 5**. **(Refer to Coverage Limitations section)**

An **intraoral bone conduction hearing system** consists of two pieces; a processor worn behind the ear and a custom fitted, removable, oral retainer-like device that works as a receiver. The intraoral system purportedly functions similar to a bone conduction hearing aid and is indicated for adults with single sided deafness. **(Refer to Coverage Limitations section)**

Semi-Implantable Middle Ear Hearing Aid

A **semi-implantable middle ear hearing aid** involves a procedure where a magnetic implant coil is wrapped around the ossicles behind the eardrum via a small incision. Electromagnetic energy then vibrates the implant which directly stimulates the inner ear or cochlea. Examples of semi-implantable middle ear hearing aids include, but may not be limited to, **Maxum Hearing Implant System** or the **Vibrant SOUNDBRIDGE System.**

Coverage Determination

Any state mandates for cochlear implants and hearing aids take precedence over this medical coverage policy.

Auditory Brainstem Implants
Implantable hearing devices, including auditory brainstem implants may be excluded by certificate. Please consult the member's individual certificate regarding Plan coverage.

If implantable hearing devices are not excluded by certificate, the following criteria applies:

Humana members may be eligible under the Plan for an FDA-approved **auditory brainstem implant** (eg, Nucleus Profile Plus Auditory Brainstem Implant), when the following criteria are met:

- 12 years of age or older; **AND**
- Diagnosed with neurofibromatosis type 2 (NF2); **AND**
- Bilateral surgical removal of auditory nerve tumors is planned and is expected to result in complete bilateral deafness or surgery has occurred and has resulted in complete bilateral deafness; **AND**
- Documentation from the physician attesting that the individual and/or family is highly motivated to participate in the postoperative programming/rehabilitation process and has realistic expectations

Humana members may be eligible under the Plan for **replacement/upgrade of auditory brainstem implants and/or its external components** when the following criteria are met:

- Existing device malfunctions or cannot be repaired; **OR**
- Replacement is required due to a change in the individual's condition that makes the present unit nonfunctional

Bone Anchored/Bone Conduction Hearing Aids
Implantable hearing devices (eg, bone anchored/bone conduction hearing aids, semi-implantable middle ear hearing aids) may be excluded by certificate. Please consult the member's individual certificate regarding Plan coverage.

If implantable hearing devices are not excluded by certificate, the following criteria applies:

Humana members may be eligible under the Plan for a **percutaneous bone anchored hearing aid (pBAHA)** or **transcutaneous bone anchored hearing aid (tBAHA)** when the following criteria are met:

- Assessment of hearing impairment has been completed by an audiologist to determine implant candidacy; **AND**
- Bone anchored/bone conduction hearing aid must be utilized in accordance with FDA-approved indications for the device, including age (see Table 1); **AND**
- Use of a conventional hearing aid is precluded by one of the following:
    - Congenital or acquired malformation of the middle/external ear (eg, congenital aural atresia, microtia, small ear canals, tumor); **OR**
    - Severe chronic otitis media

Humana members may be eligible under the Plan for **replacement/upgrade of a bone anchored/bone conduction hearing aid and/or its external components** when the following criteria are met:

- Existing device malfunctions or cannot be repaired; **OR**
- Replacement is required due to a change in the individual's condition that makes the present unit nonfunctional

Cochlear Implants

Humana members may be eligible under the Plan for a **unilateral or bilateral cochlear implant** when the following criteria are met:

- Absence of contraindications; **AND**
- Assessment of hearing impairment has been completed by an audiologist to determine implant candidacy; **AND**
- Current on age appropriate pneumococcal vaccination (2 or more weeks before surgery when possible) in accordance with Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP)[16,17]; **AND**
- Documentation from the physician attesting that the individual and/or family is highly motivated and willing to participate in the postoperative programming/rehabilitation process and has realistic expectations; **AND**
- Implant must be utilized in accordance with FDA-approved indications for the device, including age (see Table 2)

Humana members with a unilateral cochlear implant for bilateral severe to profound sensorineural hearing loss may be eligible under the Plan for **subsequent contralateral implantation**.

Humana members may be eligible under the Plan for **replacement/upgrade of a cochlear implant and/or its external components** when the following criteria are met:

- Existing device malfunctions or cannot be repaired; **OR**
- Replacement is required due to a change in the individual's condition that makes the present unit nonfunctional

Note: The criteria for **cochlear implants** are not consistent with the Medicare National Coverage Policy and therefore may not be applicable to Medicare members. Refer to the CMS website for additional information.

Semi-Implantable Middle Ear Hearing Aid

Implantable hearing devices (eg, bone anchored/bone conduction hearing aids, semi-implantable middle ear hearing aid) may be excluded by certificate. Please consult the member's individual certificate regarding Plan coverage.

If implantable hearing devices are not excluded by certificate, the following criteria applies:

Humana members may be eligible under the Plan for an FDA-approved **semi-implantable middle ear hearing aid** (eg, **Maxum Hearing Implant, Vibrant SOUNDBRIDGE system**)[78,79] when the following criteria are met:

- 18 years of age or older; **AND**
- Absence of contraindications; **AND**
- Assessment of hearing impairment has been completed by an audiologist to determine implant candidacy; **AND**
- Moderate-to-severe SNHL (no conductive hearing loss present); **AND**
- Use of a conventional hearing aid is precluded by one of the following:
    - Congenital or acquired malformation of the middle/external ear (eg, congenital aural atresia, microtia, small ear canals, tumor); **OR**
    - Severe chronic otitis media

Humana members may be eligible under the Plan for **replacement/upgrade of a semi-implantable middle ear hearing aid and/or its external components** when the following criteria are met:

- Existing device malfunctions or cannot be repaired; **OR**

- Replacement is required due to a change in the individual's condition that makes the present unit nonfunctional

Coverage Limitations

Auditory Brainstem Implants
Humana members may **NOT** be eligible under the Plan for an **auditory brainstem implant** (eg**, Nucleus Profile Plus Auditory Brainstem Implant**) for any indications other than those listed above. All other indications are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Bone Anchored/Bone Conduction Hearing Aids
Humana members may **NOT** be eligible under the Plan for the following **bone anchored/bone conduction hearing aids** (eg, **Baha [Connect] System, Ponto Bone Anchored Hearing System, Alpha 2 MPO ePlus, Baha [Attract] System, BONEBRIDGE, Osia System**) for any indications other than those listed above. All other indications are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Cochlear Implants
Humana members may **NOT** be eligible under the Plan for **cochlear implants** (eg**, HiRes Ultra, HiRes Ultra 3D, Neuro Cochlear Implant System, Nucleus Profile Plus, SYNCHRONY 2 Cochlear Implant**) for any indications other than those listed above **OR** if any of the following contraindications[74] are present:

- Absence of auditory nerve or cochlear development (eg, cochlear aplasia); **OR**
- Active inner or middle ear infections; **OR**
- Deafness due to lesions of the acoustic nerve or central auditory pathway; **OR**
- Dysfunction of the acoustic nerve; **OR**
- Tympanic membrane perforation in the presence of active middle ear disease

All other indications are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **cochlear implants for unilateral sensorineural hearing loss or asymmetric hearing loss**, as they may be excluded by certificate. Please consult the member's individual certificate regarding Plan coverage. If not excluded by certificate, these are considered not medically necessary as defined in the member's individual certificate.

Humana members may **NOT** be eligible under the Plan for a **cochlear implant for auditory neuropathy spectrum disorder/auditory neuropathy**. This is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **assistive listening devices** used alone or with a cochlear implant, as they are considered hearing aids and may be excluded by certificate. Please consult the member's individual certificate regarding Plan coverage. If not excluded by certificate, these are considered not medically necessary as defined in the member's individual certificate.

Hybrid Cochlear Implant System

Humana members may **NOT** be eligible under the Plan for a **hybrid cochlear implant system** (eg, **Nucleus Hybrid Implant System**). This is considered experimental/ investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Fully Implantable Middle Ear Hearing System

Humana members may **NOT** be eligible under the Plan for **fully implantable middle ear hearing systems** (eg, **Esteem Implant**) as they may be excluded by certificate. If not excluded by certificate, these are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Nonimplanted Hearing Devices

Humana members may **NOT** be eligible under the Plan for **nonimplanted bone conduction devices** including, but may not be limited to:

- **ADHEAR**
- **Baha Softband**
- **Baha SoundArc**
- **Ponto Softband 5**

These devices may be excluded by certificate. If not excluded by certificate, these are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for an **intraoral bone conduction hearing device**. This is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Semi-Implantable Middle Ear Hearing Aid

Humana members may **NOT** be eligible under the Plan for a **semi-implantable middle ear hearing aid** (eg, **Maxum Hearing Implant, Vibrant SOUNDBRIDGE System**) for any indications other than those listed above **OR** if any of the following contraindications[58,78,79] are present:

- Absent or nonfunctioning auditory nerve pathway **(applicable only to Vibrant SOUNDBRIDGE System)**; **OR**
- Active middle ear infection; **OR**
- Conductive hearing loss; **OR**
- Disabling tinnitus **(applicable only to Maxum Hearing Implant)**; **OR**
- Recurrent middle ear infections; **OR**
- Retrocochlear or central auditory disorder; **OR**
- Tympanic membrane perforations associated with recurrent middle ear infections

All other indications are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone	**Not Covered**
69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone	**Not Covered**
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy	**Not Covered**
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	**Not Covered**

69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy	**Not Covered**
69719	Revision or replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	**Not Covered**
69726	Removal, osseointegrated implant, skull; with percutaneous attachment to external speech processor	**Not Covered**
69727	Removal, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	**Not Covered**
69728	Removal, entire 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	**Not Covered**
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	**Not Covered**
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	**Not Covered**
69799	Unlisted procedure, middle ear	**Not Covered if used to report any implant or device outlined in Coverage Limitations section**
69930	Cochlear device implantation, with or without mastoidectomy	**Not Covered if used to report any implant outlined in Coverage Limitations section**
69949	Unlisted procedure, inner ear	**Not Covered if used to report any implant outlined in Coverage Limitations section**
92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming	
92602	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming	

92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming	
92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming	
92622	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes	**Not Covered** **New Code Effective 01/01/2024**
92623	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes (List separately in addition to code for primary procedure)	**Not Covered** **New Code Effective 01/01/2024**
92640	Diagnostic analysis with programming of auditory brainstem implant, per hour	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
L8614	Cochlear device, includes all internal and external components	**Not Covered if used to report any implant outlined in Coverage Limitations section**
L8615	Headset/headpiece for use with cochlear implant device, replacement	
L8616	Microphone for use with cochlear implant device, replacement	
L8617	Transmitting coil for use with cochlear implant device, replacement	
L8618	Transmitter cable for use with cochlear implant device or auditory osseointegrated device, replacement	**Not Covered if used to report any device outlined in Coverage Limitations section**
L8619	Cochlear implant, external speech processor and controller, integrated system, replacement	**Not Covered if used to report any device outlined in Coverage Limitations section**
L8621	Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each	**Not Covered if used to report any device outlined in Coverage Limitations section**
L8622	Alkaline battery for use with cochlear implant device, any size, replacement, each	

L8623	Lithium ion battery for use with cochlear implant device speech processor, other than ear level, replacement, each	
L8624	Lithium ion battery for use with cochlear implant or auditory osseointegrated device speech processor, ear level, replacement, each	**Not Covered if used to report any device outlined in Coverage Limitations section**
L8625	External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each	**Not Covered if used to report any device outlined in Coverage Limitations section**
L8627	Cochlear implant, external speech processor, component, replacement	
L8628	Cochlear implant, external controller component, replacement	
L8629	Transmitting coil and cable, integrated, for use with cochlear implant device, replacement	
L8690	Auditory osseointegrated device, includes all internal and external components	**Not Covered**
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each	**Not Covered**
L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment	**Not Covered**
L8693	Auditory osseointegrated device abutment, any length, replacement only	**Not Covered**
L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each	**Not Covered**
L8699	Prosthetic implant, not otherwise specified	**Not Covered if used to report any implant or device outlined in Coverage Limitations section**
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear	**Not Covered**
S2235	Implantation of auditory brain stem implant	
V5095	Semi-implantable middle ear hearing prosthesis	**Not Covered**
V5267	Hearing aid or assistive listening device/supplies/accessories, not otherwise specified	**Not Covered**
V5268	Assistive listening device, telephone amplifier, any type	**Not Covered**
V5270	Assistive listening device, television amplifier, any type	**Not Covered**
V5271	Assistive listening device, television caption decoder	**Not Covered**
V5272	Assistive listening device, TDD	**Not Covered**
V5273	Assistive listening device, for use with cochlear implant	**Not Covered**

V5274	Assistive listening device, not otherwise specified	**Not Covered**
V5281	Assistive listening device, personal FM/DM system, monaural (1 receiver, transmitter, microphone), any type	**Not Covered**
V5282	Assistive listening device, personal FM/DM system, binaural (2 receivers, transmitter, microphone), any type	**Not Covered**
V5283	Assistive listening device, personal FM/DM neck, loop induction receiver	**Not Covered**
V5284	Assistive listening device, personal FM/DM, ear level receiver	**Not Covered**
V5285	Assistive listening device, personal FM/DM, direct audio input receiver	**Not Covered**
V5286	Assistive listening device, personal blue tooth FM/DM receiver	**Not Covered**
V5287	Assistive listening device, personal FM/DM receiver, not otherwise specified	**Not Covered**
V5288	Assistive listening device, personal FM/DM transmitter assistive listening device	**Not Covered**
V5289	Assistive listening device, personal FM/DM adapter/boot coupling device for receiver, any type	**Not Covered**
V5290	Assistive listening device, transmitter microphone, any type	**Not Covered**

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Appendix

Appendix A – Degree of Hearing Loss[15]

Degree of Hearing Loss	Hearing Loss Range (dB HL = decibels hearing level)
Normal Hearing	-10 to 15 dB HL
Slight	16 to 25 dB HL
Mild	26 to 40 dB HL
Moderate	41 to 55 dB HL
Moderately Severe	56 to 70 dB HL
Severe	71 to 90 dB HL
Profound	91 dB HL or greater

Appendix B – Hearing Tests

Early Speech Perception Test (ESP) – Pattern perception, two syllable word (with equal emphasis on both syllables) identification and monosyllable identification are assessed with a response format of pictured vocabulary or toy manipulatives.

Hearing In Noise Test (HINT) – Individual uses binaural hearing to repeat sentences in both quiet and with various levels of competing noise being scored on the accuracy of their responses; version available for children as well.

Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) – Modification of the MAIS (see below) that is a structured interview designed to assess an infant or toddler's spontaneous responses to sound in his/her everyday environment; based on information provided by the child's parents.

Lexical Neighborhood Test (LNT) – Open-set test of word understanding which includes vocabulary familiar to children ages three to five; this version uses single syllable words.

Meaningful Auditory Integration Scale (MAIS) – Evaluates use of sound in everyday situations by profoundly hearing-impaired children in regard to three main areas of vocalization behavior, alerting to sounds and deriving meaning from sound; information about the use of sound in everyday situations is obtained with a parent interview.

Multisyllabic Lexical Neighborhood Test (MLNT) – Open-set test of word understanding which includes vocabulary familiar to children ages three to five; this version uses two and three syllable words.

Phonetically Balanced-Kindergarten Word Test (PBK) – Consists of four 50 word lists composed of kindergarten vocabulary presented in an open-set format; the tester presents the words verbally and the child is asked to repeat the word; scored on accuracy.

Table 1
FDA-Approved Bone Anchored/Bone Conduction Hearing Aids and Indications

pBAHA[68,71]	**FDA Indications**
Baha [Connect] System **Ponto Bone Anchored Hearing System**	• 5 years of age or older; **AND** • Pure tone average bone conduction hearing threshold less than or equal to 65 dB HL; **AND** either of the following: • Bilateral placement: Bilaterally symmetric (10 dB average difference between ears or less than 15 dB difference at individual frequencies) moderate-to-severe conductive or mixed hearing loss; **OR** • Unilateral placement: Profound SNHL in one ear and normal hearing in the opposite ear (eg, single sided deafness [SSD])
tBAHA[67,69,70,72]	**FDA Indications**
Alpha 2 MPO ePlus **Baha [Attract] System** **BONEBRIDGE** **Osia System**	• 5 years of age or older (for **Alpha 2 MPO ePlus** and **Baha [Attract] System**) **OR** 12 years of age or older (for **BONEBRIDGE** and **Osia System**); **AND** • Pure tone average bone conduction hearing threshold less than or equal to 65 dB HL; **AND** either of the following: • Bilateral placement: Bilaterally symmetric (10 dB average difference between ears or less than 15 dB difference at individual frequencies) moderate-to-severe conductive or mixed hearing loss; **OR** • Unilateral placement: Profound SNHL in one ear and normal hearing in the opposite ear (eg, SSD)

Table 2
FDA-Approved Cochlear Implants and Indications[73,75,77]

Cochlear Implants	FDA Indications
HiRes Ultra/HiRes Ultra 3D Cochlear Implant	**Adults** • 18 years of age or older; **AND** • Postlingual onset of severe-to-profound bilateral SNHL defined as greater than 70 dB HL; **AND** • Limited benefit from appropriately fitted hearing aids, defined as scoring 50% or less on a test of open set sentence recognition (HINT) **Children** • 12 months through 17 years of age; **AND** • Profound bilateral sensorineural deafness defined as greater than 90 dB HL; **AND** • Use of appropriately fitted hearing aids *(The minimum duration of hearing aid use is waived if X-rays indicate ossification of the cochlea.)* ○ For at least 6 months in children 2 through 17 years of age; **OR** ○ For at least 3 months in children 12 through 23 months of age; **AND** • Little or no benefit from appropriately fitted hearing aids, which is defined as: ○ In children less than 4 years of age, lack of benefit is defined as a failure to reach developmentally appropriate auditory milestones (eg, spontaneous response to name in quiet or to environmental sounds) measured using the IT-MAIS/MAIS or less than 20% correct on a simple open-set word recognition test (MLNT) administered using monitored live voice (70 dB sound pressure level [SPL]); **OR**

Cochlear Implants	FDA Indications
	○ In children 4 years of age or older, lack of hearing aid benefit is defined as scoring less than 12% on a difficult open-set word recognition test (PBK) or less than 30% on an open-set sentence test (HINT) administered using recorded materials in the sound field (70 dB SPL)
Neuro Cochlear Implant System	**Adults** • 18 years of age or older; **AND** • Bilateral severe-to-profound SNHL defined as a pure tone average (PTA) greater than or equal to 70 dB HL at 500, 1000 and 2000 Hz; **AND** • Limited benefit from a 3 month trial of hearing aids, as defined by test scores less than or equal to 50% correct on HINT sentences with best-aided listening condition
Nucleus Profile Plus Cochlear Implant System	**Adults** • 18 years of age or older; **AND** • Bilateral, pre-, peri- or post-linguistic sensorineural hearing impairment of moderate-to-profound hearing loss in the low frequencies **and** profound hearing loss defined as greater than or equal to 90 dB HL in the mid to high speech frequencies; **AND** • Limited benefit from appropriate binaural hearing aids, as defined by test scores of 50% correct or less in the ear to be implanted (60% or less in the best aided listening condition) on tape recorded tests of open set sentence recognition **Children** • Children 9 to 24 months of age who have bilateral profound sensorineural deafness **OR** children 2 years of age or older who demonstrate severe-to-profound hearing loss bilaterally; **AND** • Limited benefit from appropriate binaural hearing aids, which is defined as:

Cochlear Implants	FDA Indications
	○ In younger children, lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three to six month period. It is recommended that limited benefit be quantified on a measure such as the MAIS or the ESP test; **OR** ○ In older children, limited benefit from a 3 to 6 month trial of hearing aids, as defined by test scores less than or equal to 30% correct on the open set MLNT or LNT, depending upon the child's cognitive and linguistic skills
SYNCHRONY 2 Cochlear Implant	**Adults** • 18 years of age of older; **AND** • Bilateral severe-to-profound SNHL defined as a PTA greater than or equal to 70 dB HL at 500 Hz, 1000 Hz and 2000 Hz; **AND** • Limited benefit from appropriate binaural hearing aids defined as 40% correct or less on HINT sentences with best-aided listening conditions **Children** • 12 months through 17 years of age with bilateral profound SNHL with thresholds greater than or equal to 90 dB HL at 1000 Hz; **AND** • 3 to 6 month trial with hearing aids; **AND** *(Radiologic evidence of cochlear ossification may justify a shorter trial with amplification*.) • Limited benefit from appropriate binaural hearing aids, which is defined as: ○ In younger children, lack of progress in the development of simple auditory skills with appropriate amplification and participation in intensive aural habilitation over a 3 to 6 month period; **OR**

Cochlear Implants	FDA Indications
	○ In older children, lack of aided benefit is defined as less than 20% correct on the MLNT or LNT depending upon the child's cognitive ability and linguistic skills

Change Summary

- 03/28/2024 Annual Review, No Coverage Change.