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Health Plans

Medicare Advantage

X Commercial

Cochlear Implants and Osseo-integrated Bone Conduction Devices Policy

I. Purpose

Indiana University Health Plans (IU Health Plans) considers clinical indications when making a medical necessity determination for Cochlear Implants and Osseo-integrated Bone Conduction Devices.

II. Scope

This policy applies to all Utilization Management staff having decision-making responsibilities where authorization is required for Full-insured commercial plans.

III. Exception/Variations

1. Those with cochlear implants may be at a particularly increased risk for pneumococcal meningitis. Cochlear implant recipients and all potential implant recipients must be up to date with age-appropriate recommended vaccinations according to the CDC/Advisory Committee on Immunization Practices (ACIP) to prevent pneumococcal infections.
2. Cochlear implantation may be covered for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification.
3. The replacement of existing external components with upgraded components when done solely to improve appearance or to treat psychological symptomatology or complaints because it is considered not medically necessary and will not be covered.

IV. Definitions

Cochlear Implant Device- According to Center for Medicare and Medicaid Services (CMS), a cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single and multi-channel models. The purpose of the implant is to provide awareness and identification of sounds and to facilitate communication for persons who have moderate to profound hearing loss.

Conductive Hearing Loss- Hearing loss primarily in the external and middle ear.

Sensorineural Hearing Loss- Hearing loss which results when there is damage to the inner ear.

V. Policy Statements

IU Health Plans considers **Cochlear implants and Osseointegrated Bone Conduction Devices** medically necessary for **one or more of the following** indications:

1. Adults (ages 18 and over) must meet **all of the following**:
 - a. Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids. Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence recognition in the ear to be implanted and 60% or less in the non-implanted ear bilaterally.
 - b. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation.
 - c. Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation and freedom from significantly compromising lesions in the auditory nerve and acoustic areas of the central nervous system.
 - d. No contraindications to surgery.
 - e. The device must be used in accordance with FDA approved labeling for that specific model.
 - f. Cochlear implantation may be covered for individuals meeting the selection guidelines above and with hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in any of the following:
 1. An FDA-approved category B investigational device exemption (IDE) clinical trial
 2. A trial approved or under the supervision of CMS.
2. Children (ages >1 through 17 years old) must meet **one or more of the following**:
 - a. **All of the following** must meet for sudden hearing loss from meningitis:
 1. An absence of medical contraindications, such as chronic middle ear pathology, some lesions of the VIIIth cranial nerve, some pathologies of the central auditory pathway, and other medical issues that preclude surgical procedures
 2. Family commitment to post-implant appointments and the rehabilitation process and realistic expectations for cochlear implant use and benefit.
 3. For children without previous experience with hearing aids and a 3 to 6-month hearing aid trial has been attempted and failed.
 4. The device must be used in accordance with FDA approved labeling for that specific model.
 5. Vaccinations are up to date
 - b. **All of the following** must meet for all other indications:
 1. Diagnosis of bilateral severe- to- profound sensorineural hearing loss
 2. The child has limited benefit from appropriately fitted bilateral hearing aids. Limited benefit is defined as **one of the following**:
 - a. Less than 12% correct on the Phonetically Balanced-Kindergarten Test

- b. Less than 30% correct on the Hearing in Noise Test, the Open-Set Multisyllabic Lexical Neighborhood Test or Lexical Neighborhood Test depending on the child's cognitive ability and linguistic skills.
 3. An absence of medical contraindications, such as chronic middle ear pathology, some lesions of the VIIIth cranial nerve, some pathologies of the central auditory pathway, and other medical issues that preclude surgical procedures
 4. Family commitment to post-implant appointments and the rehabilitation process and realistic expectations for cochlear implant use and benefit.
 5. For children without previous experience with hearing aids and a 3- 6 month hearing aid trial has been attempted and failed.
 6. The device must be used in accordance with FDA approved labeling for that specific model.
 7. Vaccinations are up to date
3. Bilateral Cochlear Implantation Surgery must meet **all of the following**:
 1. The physician's and cochlear implant team's expectations for improved performance in the second ear with binaural use.
 2. Reasonable and realistic expectations of the anticipated benefit from the second implant from the patient and their family.
 3. The absence of medical or surgical contraindications for the patient to undergo surgical intervention indicated by **one of the following**:
 1. Chronic ear disease in the second ear
 2. Tympanic membrane perforation
 3. Cochlear canal anatomy precluding successful implantation
 4. Deafness in the second ear for >20 years that has been without aural amplification (a hearing aid should have been used during this time period)
 - d Must meet **one or more of the following** for Bilateral Cochlear Implantation:
 1. For Bilateral Simultaneous Implantation, **one of the following** must be met:
 - a Bilateral hearing loss in the "profound" audiometric range for both ears since birth
 - b. Normal labyrinthine, mastoid, middle ear and ear canal anatomy
 - c. Recent history of meningitis
 2. For Bilateral Sequential Implantation in members already unilaterally implanted, **all of the following** must be met:
 - a. Second ear must meet cochlear implant candidacy criteria as described above for unilateral implants at the time of the initial evaluation for the first cochlear implant
 - b. Member should have developed reasonable abilities in the implanted ear
 - c. The second ear is a potential candidate if the first side did not achieve sufficient function due to complications or unanticipated outcome due to it being the poorer hearing ear at time of original implantation.
4. Bone Anchored Hearing Aid (BAHA) Implants must meet **one of the following**:
 - a. Unilateral BAHA Implants must meet **all of the following**:
 1. The audiometric criterion of the candidate with a conductive or mixed hearing loss that is not correctible in at least one ear by medical or surgical intervention
 - 2 The patient is unable to use conventional air conduction hearing aid due to a congenital malformation of the external ear canal or middle ear, chronic otitis, or active chronic suppurative otitis media, tumors of the external ear canal, or

- refractory dermatitis of the external canal
3. A patient with profound sensorineural hearing loss and normal hearing in the opposite ear defined as a 20 dBHL air conduction pure tone average (0.5K, 1K, 2K, and 3K) is considered a BARA candidate
4. The patient meets FDA audiologic criteria for use of the specific model requested
5. Must be 5 years old or older
- b. Bilateral BARA Implantation must meet **all of the following** (includes second implant):
 1. The audiometric criterion of the candidate with a conductive or mixed hearing loss is a 45 dBHL bone conduction pure tone average (0.5K, 1K, 2K, 3K) and 60% monosyllabic word score in the indicated ear. The patient can have a bilateral or unilateral conductive hearing loss
 2. Hearing loss that is not correctible in at least one ear by medical or surgical intervention
 3. The patient is unable to use conventional air conduction hearing aid due to a congenital malformation of the external ear canal or middle ear, chronic otitis, or active chronic suppurative otitis media, tumors of the external ear canal, or refractory dermatitis of the external canal
 4. A patient with profound sensorineural hearing loss and normal hearing in the opposite ear defined as a 20 dBHL air conduction pure tone average (0.5K, 1 K, 2K, and 3K) is considered a BARA candidate
 5. The patient meets FDA audiologic criteria for use of the specific model requested
 6. Must be 5 years old or older
 7. Must meeting **one of the following**:
 - a. Less than 10 dB difference on average between ears (average of 0.5, 1, 2, and 3kHz)
 - b. Less than 15 dB difference at individual frequencies between ears
5. Replacements and upgrades must meet **one or more of the following**:
 - a. Replacements must meet **one or more of the following**:
 1. The currently used component is no longer functional and the component cannot be repaired
 2. The currently used component renders the implant recipient unable to adequately and/or safely perform his/her appropriate activities of daily living
 - b. Upgrades must meet **one or more of the following**:
 1. The currently used component is no longer functional and the component cannot be repaired
 2. The currently used component renders the implant recipient unable to adequately and/or safely perform his/her age-appropriate activities of daily living
 3. The upgrade is shown to have significant improvement in the patient's listening and speech performance
 4. Upgraded technology offers significant potential to improve functionality

Codes:

CODE	DESCRIPTION
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone (Replacement procedure includes removal of old device)

69711	Removal or repair 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
69717	Revision or replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor
69719	Revision or replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
69726	Removal, osseointegrated implant, skull; with percutaneous attachment to external speech processor
69727	Removal, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
69930	Cochlear device implantation, with or without mastoidectomy
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
92700	Unlisted otorhinolaryngological service or procedure (Example: May be used to cover fitting of sound processor.)
L8614	Cochlear device, includes all internal and external components
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, replacement
L8619	Cochlear implant, external speech processor and controller, integrated system, replacement
L8621	Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each
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
L8625	External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only
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

L8691	Auditory osseointegrated device, external sound processor, replacement
L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment (Softband or SoundArc with sound processor) Baba Softband System or Baba SoundArc System
L8693	Auditory osseointegrated device abutment, any length, replacement only
L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each request
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
V5040	Body-worn hearing aid bone
V5273	Assistive listening device, for use with cochlear implant

VI. Procedures

None

VII. References/Citations

1. American Speech-Language-Hearing Association (ASHA) (1997-2023). Cochlear Implants. [Cochlear Implants \(asha.org\)](https://www.asha.org/public/hearing/cochlear-implants/)
2. Center for Disease Control and Prevention (CDC) - Vaccines and Preventable Diseases. Cochlear Implants and Vaccination Recommendations. Last reviewed September 21,2023. [Cochlear Implants and Vaccination Recommendations: Information for Public | CDC](https://www.cdc.gov/vaccines/imz/downloads/coclear-implants-and-vaccination-recommendations-information-for-public.pdf)
3. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) Cochlear Implantation. 50.3. Implementation Date: 03/24/2023. [NCD - Cochlear Implantation \(50.3\) \(cms.gov\)](https://www.cms.gov/medicare/coverage/determinations/national-coverage-determinations-coclear-implantation-503)
4. FDA. U.S. Food & Drug Administration. Benefits and Risks of Cochlear Implants. Current as of 2/9/2021. [Benefits and Risks of Cochlear Implants, FDA](https://www.fda.gov/medical-devices/cochlear-implants/benefits-and-risks-of-cochlear-implants)
5. Tarabichi, O., Jensen, M., & Hansen, M. R. (2021). Advances in hearing preservation in cochlear implant surgery. *Current opinion in otolaryngology & head and neck surgery*, 29(5), 385-390. <https://doi.org/10.1097/MOO.0000000000000742>

VIII. Forms/Appendices

None

IX. Responsibility

Medical Director

This Policy is proprietary and confidential. No part of this Policy may be disclosed in any manner to a third party without the prior written consent of IU Health Plans, Inc.