Medical Affairs Policy

Service: Cochlear Implants, Bone Anchored Hearing Aids (BAHA), Auditory Brainstem Implants, and other hearing assistive devices

PUM 250-0014

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<th>Arise/WPS Policy Committee Approval</th>
<th>06/03/16</th>
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<td>Effective Date</td>
<td>10/01/16</td>
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<td>Prior Authorization Needed</td>
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Disclaimer: This policy is for informational purposes only and does not constitute medical advice, plan authorization, an explanation of benefits, or a guarantee of payment. Benefit plans vary in coverage and some plans may not provide coverage for all services listed in this policy. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and federal law. Some benefit plans administered by Wisconsin Physicians Service and Arise Health Plan (WPS/AHP) may not utilize WPS/AHP medical policy in all their coverage determinations. Contact customer services as listed on the member card for specific plan, benefit, and network status information.

Medical policies are based on constantly changing medical science and are reviewed annually and subject to change. WPS/AHP uses tools developed by third parties, such as the evidence-based clinical guidelines developed by MCG Health® to assist in administering health benefits. This medical policy and MCG Health® guidelines are intended to be used in conjunction with the independent professional medical judgment of a qualified health care provider. To obtain additional information about MCG email medical.policies@wpsic.com.

Description:

A cochlear implant is an implantable prosthetic device that processes sounds electronically then transmits electronic stimulation to the cochlea resulting in a sense of sound to individuals with hearing loss. The device includes a microphone, sound processor, batteries, and a transmitter that sends coded electrical information and power to the internal parts. The internal components are placed surgically underneath the skin and include a receiver and an electrode array within the cochlea.

A bone-anchored hearing aid (BAHA) is a type of hearing aid that provides sound conduction through a titanium implant implanted in one of the bones of the skull. The BAHA consists of 3 parts: a titanium implant, an external abutment, and a sound processor. The BAHA transmits vibrations through the skull bone to the cochlea without being transmitted through the middle ear.

Auditory Brainstem Implant (ABI) is a modification of the cochlear implant, in which the electrode array is placed directly into the brain. The device designed to restore some hearing in an individual when cochlear implant is not indicated because of cochlear or auditory nerve abnormalities.

Additional devices include semi-implantable hearing aids, and prosthetic hearing assistive devices.
Note: Cochlear implants are not considered hearing aids. BAHAs are considered hearing aids.

When deciding coverage, reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific certificate must be referenced prior to using the medical policy. In the event of a conflict, the enrollee's specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, or when the member’s certificate is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice.

**Indications of Coverage:**

**A.** Cochlear implants (Unilateral, Bilateral sequential or Bilateral simultaneous) are considered medically necessary for individuals age 18 years or older when **ALL** of the following criteria are met:

1. Severe post-lingual bilateral sensorineural hearing impairment (pure-tone average of 70 decibels or higher at 500, 1,000, and 2,000 hertz)

2. Less than 50% score on standardized open-set sentence recognition test in ear to be implanted and less than 60% in contralateral ear when using appropriately fitted hearing aids

3. An evaluation by an audiologist and an otolaryngologist experienced with cochlear implantation indicates the likelihood of success following the implantation of the device

4. MRI confirmation of intact cochlea and cochlear nerve

5. Documentation that the current CDC recommendations for immunization of persons with cochlear implants have been discussed with the patient. (See: [http://www.cdc.gov/vaccines/vpd-vac/pneumo/vac-PCV13-adults.htm](http://www.cdc.gov/vaccines/vpd-vac/pneumo/vac-PCV13-adults.htm))

**B.** Cochlear implants (Unilateral, Bilateral sequential or Bilateral simultaneous) are considered medically necessary for individuals’ from age 5 months to the 18th birthday when **ALL** of the following criteria are met:

1. Severe bilateral sensorineural hearing impairment (unaided pure-tone average of at least 90 decibels or louder at 1,000 hertz)
2. Minimal speech perception (30% or less) or lack of developmentally appropriate auditory milestones measured using parental report scales

3. A three-month trial of binaural hearing aids documents lack of or minimal improvement in auditory development.

4. An evaluation by an audiologist and an otolaryngologist experienced with cochlear implantation indicates the likelihood of success following the implantation of the device (e.g. NO evidence of central auditory dysfunction or auditory nerve or cochleovestibular anomaly: cochlear aplasia, complete labyrinthine aplasia, lack of cochlear nerve, or vestibular schwannoma excision planned and cochlear nerve preservation thought possible)

5. Documentation that the current CDC recommendations for immunization of persons with cochlear implants have been discussed with the patient or guardian. (See: http://www.cdc.gov/vaccines/vpd-vac/mening/cochlear/dis-cochlear-faq-hcp.htm and http://www.cdc.gov/vaccines/vpd-vac/mening/cochlear/dis-cochlear-gen.htm)


D. BAHAs are considered medically necessary for individuals older than five (5) years* with bilateral conductive or bilateral mixed (conductive and sensorineural) hearing loss when ALL of the following criteria are met:

1. An air-conduction hearing aid is contraindicated, failed, or not appropriate

2. Pure tone average bone conduction threshold (measured at 0.5, 1, 2, and 3 kHz) less than or equal to 45 dB HL, or level appropriate for model to be implanted (per the documentation provided)

3. Speech discrimination of the indicated ear of 60% or more at elevated sound pressure levels (SPL) during speech discrimination testing using consonant–nucleus–consonant (CNC) words (conventional) testing

4. Cortical bone thickness of 3 mm or more

5. Documentation of at least ONE of the following conditions:

   a. Severe chronic ear infection (for example, external otitis or otitis media)

   b. Malformations of the external or middle ear canal (either congenital or the result of surgery)
c. Tumors of the ear canal

d. Lack of substantial audiologic improvement with air conduction

➤ Note: If a child under age five (5) meets all other criteria above including the cortical bone thickness, the “older than five years” criteria may be waived.

E. Bilateral BAHA is considered medically necessary when all of the criteria in section D. are met AND there is a symmetrical conductive or mixed hearing loss as defined by a difference between left and right side bone conduction threshold of less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz (4 kHz for OBC and Ponto Pro), or less than 15 dB at individual frequencies.

F. BAHA may be considered medically necessary as an alternative to an air-conduction hearing aid (including CROS contralateral-routing signal aids) in individuals from age 5 years to the 18th birthday, with single-sided sensorineural deafness (≥70 dB) and normal hearing in the other ear. The pure tone average air conduction threshold of the normal ear should be better than 20 dB measured at 0.5, 1, 2, and 3 kHz, and pure tone average bone conduction threshold (measured at 0.5, 1, 2, and 3 kHz) should be less than or equal to 45 dB HL.

G. Replacement components for an existing system are considered medically necessary when the current component is not functional and cannot be repaired or when the current component is no longer adequate for the individual’s daily activities (for example, due to age-appropriate changes in the individual’s capabilities) and improvement is expected with the new component. Replacement or upgrades of components to improve the individual’s appearance or due to psychosocial concerns is not medically necessary. Components are generally expected to be useable for a period of three years. The member’s certificate must be referenced to determine the DME benefits for repair or replacement of external components

**Limitations of Coverage:**

A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.

B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental, investigational, and unproven to affect health outcomes.

C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.
D. Cochlear implants for unilateral (single sided) deafness are considered experimental, investigational, and unproven to affect health outcomes.

E. Cochlear implants are considered not medically necessary when any of the following are documented:

1. Cochlear aplasia (failure of cochlear development)
2. Acute middle ear infection
3. Dysfunctional acoustic nerve
4. Cancer of the head or neck
5. Replacement or upgrades of components are ordered to improve the individuals’ appearance or due to psychosocial concerns

F. Implantable and Semi-implantable hearing aids and transducer systems are considered experimental, investigational, unproven to affect health outcomes.

G. Electric-acoustic stimulation (EAS) devices combining the functions of a cochlear implant with a hearing aid (e.g. Nucleus Hybrid L24 Implant System) are considered experimental, investigational, and unproven to affect health outcomes.

H. Semi-implantable Electromagnetic Hearing Aides and Transducer systems are considered experimental, investigational, and unproven to affect health outcomes.

J. Maxim System is considered experimental, investigational, and unproven to affect health outcomes.

K. Lyric and Lyric2 Hearing Aid systems are considered experimental, investigational, and unproven to affect health outcomes.

L. Vibrant Soundbridge System, the Soundtec Direct Drive system, or the semi-implantable Middle Ear Transducer (MET) Ossicular Stimulator System are considered experimental, investigational, and unproven to affect health outcomes.

M. Esteem Hearing Implant (Implantable Middle Ear hearing aid) is considered experimental, investigational, and unproven to affect health outcomes.
N. Ponto Plus and Ponto Plus PowerBone anchored hearing aid for unilateral conductive hearing loss are considered experimental, investigational, and unproven to affect health outcomes.

O. Bilateral (binaural) cochlear implants, in individuals over age 18, who are pre-lingually deafened, have moderate deafness or other disabilities or structural abnormalities that could interfere with the procedure, are considered investigative as there is insufficient peer-reviewed scientific literature in these populations.

P. BAHAs are considered investigational and unproven for individuals with bilateral pure sensorineural hearing loss.

Q. BAHAs are considered investigational and unproven for individuals over age 18 with normal hearing in one ear (unilateral sensorineural deafness) as there is insufficient peer-reviewed scientific literature supporting the use of BAHAs in these individuals.

Documentation Required:

- Office notes
- Test results, including audiogram (pure tone and bone conduction) report

References:


17. Hayes HTB Nucleus Hybrid L24 Implant System Published Jul 9, 2015


22. Cochlear implants for children and adults with severe to profound deafness. Issue date: January 2009 Review Date Feb 2011. NICE Technology Appraisal

23. UpToDate™ Hearing Amplification in Adults. Topic Last Updated April 25, 2016


27. UpToDate™ Hearing impairment in children: Treatment. Topic Last Updated Feb 17, 2016


Review History:

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> Note: For review/revision history prior to 2014 see previous Medical Policy or Coverage Policy Bulletin

Approved by the Medical Director