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Medical Policy Cochlear Implant

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Policy Number: 478

BCBSA Reference Number: 7.01.05 (For Plans internal use only)

Related Policies

- Auditory Brainstem Implant, #481
- Implantable Bone-Conduction and Bone-Anchored Hearing Aids, #479
- Semi-Implantable and Fully Implantable Middle Ear Hearing Aid, #480
- Treatment of Tinnitus, #267

Policy¹

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Cochlear implantation of a U.S. Food and Drug Administration (FDA) – approved cochlear implant device may be <u>MEDICALLY NECESSARY</u> in patients age 9 months and older when criteria 1-3 are met:

- 1. Patient has been diagnosed with **one** of the following:
 - a. Bilateral hearing loss defined as behavioral audiometric recorded word/sentence testing score (e.g. consonant-nucleus-consonant CNC) of ≤ 60% in the best aided binaural condition or Auditory Brainstem Response (ABR) hearing thresholds ≥ 70 dB (decibels) hearing level at frequencies 1000, 2000, and 4000 Hz (Hertz) who have shown limited or no benefit from hearing aids, OR
 - b. Unilateral Hearing Loss (UHL) includes Single Sided Deafness (SSD)
 - i. Absence of usable hearing in one ear (recorded word/sentence testing score ≤ 40% or ABR thresholds ≥ 70dB at frequencies 1000, 2000, and 4000 Hz); AND
 - ii. Normal to near-normal hearing in the contralateral ear (of note: hearing aid trial is not required if patient meets the above criteria), **OR**
 - c. Asymmetric Hearing Loss (AHL)
 - i. Absence of usable hearing in one ear (recorded word/sentence testing score ≤ 40% or ABR thresholds ≥ 70dB at frequencies 1000, 2000, and

- 4000 Hz). (Of note: hearing aid trial is not required if patient meets this criteria): **AND**
- Sensorineural hearing loss in the other ear that is usable (recorded word/ sentence testing score > 60% or ABR thresholds < 70dB at frequencies 1000, 2000, and 4000 Hz).
- 2. Inner ear anatomy is expected to support cochlear implantation, AND
- 3. None of the following contraindications are present:
 - a. Absent cochlea or known absent cochlear nerve (e.g., post trauma or post-surgical)
 - b. Major cochlear ossification (defined as obliteration of both scala tympani and scala vestibuli in two or more turns of the cochlea)
 - c. Otologic conditions that contraindicate surgery, such as:
 - i. Active middle ear or mastoid infection
 - ii. Tympanic membrane perforation
 - d. Evidence of retrocochlear pathology (brainstem lesions involving cochlear nucleus, severe central auditory processing disorder)

Cochlear implantation as not otherwise meeting above criteria is INVESTIGATIONAL.

Upgrades of an existing, functioning external system to achieve aesthetic improvement, such as smaller profile components or a switch from a body-worn, external sound processor to a behind-the-ear model, are **NOT MEDICALLY NECESSARY**.

Replacement of internal and/or external components solely for the purpose of upgrading to a system with advanced technology or to a next-generation device is considered **NOT MEDICALLY NECESSARY**.

Providers should determine the reasonable useful lifetime of the device to be five years—see DME
Payment Policy.

Replacement of internal and/or external components is considered <u>MEDICALLY NECESSARY</u> only in a small subset of members who have inadequate response to existing component(s) to the point of interfering with the individual's activities of daily living, or the component(s) is/are no longer functional and cannot be repaired. Copies of original medical records must be submitted either hard copy or electronically to support medical necessity.

Cochlear implantation with a hybrid cochlear implant/hearing aid device that includes the hearing aid integrated into the external sound processor of the cochlear implant (e.g., the Nucleus® Hybrid™ L24 Cochlear Implant System) may be considered MEDICALLY NECESSARY for patients ages 18 years and older who meet all of the following criteria:

- Bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity;
- Receive limited benefit from appropriately fitted bilateral hearing aids; AND
- Have the following hearing thresholds:
 - \circ Low-frequency hearing thresholds \le 60 dB at frequencies 125, 250, and 500 Hz in the ear selected for implantation; **AND**
 - Severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥75 dB hearing level) in the ear to be implanted; AND
 - Moderately severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥ 60 dB hearing level) in the contralateral ear; **AND**
 - Recorded word/sentence testing score from 10% to 60% in the ear to be implanted in the
 preoperative aided condition and in the contralateral ear will be equal to or better than that of
 the ear to be implanted, but not more than 80% correct.

Prior Authorization Information

Inpatient

• For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

• For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes:

CPT codes:	Code Description
69930	Cochlear device implantation, with or without mastoidectomy

HCPCS Codes

HCPCS	
codes:	Code Description
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 or auditory osseointegrated
	device, replacement
L8619	Cochlear implant, external speech processor and controller, integrated system,
	replacement
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

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and HCPCS codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

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ICD-10-CM	
Diagnosis	
codes:	Code Description

H90.3	Sensorineural hearing loss, bilateral
	Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the
H90.41	contralateral side
	Sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the
H90.42	contralateral side
H90.5	Unspecified sensorineural hearing loss

Description

The basic structure of a cochlear implant includes both external and internal components. The external components include a microphone, an external sound processor, and an external transmitter. The internal components are implanted surgically and include an internal receiver implanted within the temporal bone and an electrode array that extends from the receiver into the cochlea through a surgically created opening in the round window of the middle ear.

Sounds picked up by the microphone are carried to the external sound processor, which transforms sound into coded signals that are then transmitted transcutaneously to the implanted internal receiver. The receiver converts the incoming signals into electrical impulses that are then conveyed to the electrode array, ultimately resulting in stimulation of the auditory nerve.

Summary

A cochlear implant is a device for treatment of severe-to-profound hearing loss in individuals who only receive limited benefit from amplification with hearing aids. A cochlear implant provides direct electrical stimulation to the auditory nerve, bypassing the usual transducer cells that are absent or nonfunctional in deaf cochlea.

For individuals who have bilateral sensorineural hearing loss who receive the cochlear implant(s), the evidence includes randomized controlled trials (RCTs) and multiple systematic reviews and technology assessments. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. The available studies have reported improvements in speech reception and quality of life measures. Although the available RCTs and other studies measured heterogeneous outcomes and included varying patient populations, the findings are consistent across multiple studies and settings. In addition to consistent improvement in speech reception (especially in noise), studies showed improvements in sound localization with bilateral devices. Studies have also suggested that earlier implantation may be preferred. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive the cochlear implant(s), the evidence includes a feasibility study, prospective and retrospective studies reporting within-subjects comparisons, systematic reviews of observational studies, a multicenter, prospective, open, nonrandomized clinical trial, and a longitudinal, prospective, Food and Drug Administration-approved study of cochlear implantation for unilateral sensorineural hearing loss patients. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. Given the natural history of hearing loss, pre- and post-implantation comparisons may be appropriate for objectively measured outcomes. Otherwise, the available evidence for the use of cochlear implants in improving outcomes for patients with unilateral hearing loss, with or without tinnitus, is limited by small sample sizes and heterogeneity in evaluation protocols and outcome measurements. A small feasibility study in adults with single-sided deafness or asymmetric hearing loss demonstrated improvements in sound perception, sound localization, and subjective measures of quality of life compared to baseline conditions. Studies assessing outcomes compared to best-aided hearing controls across multiple time points are lacking. Despite limitations in the current level of evidence, subgroup analyses show improvement in hearing for specific populations and expert consensus supports cochlear implantation for unilateral hearing loss when other currently available treatments are unlikely to benefit the patient. The available studies have reported improvements in speech reception, improved speech understanding, quality of life measures and the

clinical benefit of cochlear implantation in patients with unilateral sensorineural hearing loss. The present behavioral and subjective data suggest that unilateral sensorineural hearing loss patients greatly benefit from cochlear implantation. An ongoing post-marketing study in adults and children may further elucidate outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a high-frequency sensorineural hearing loss with preserved low-frequency hearing who receive a hybrid cochlear implant that includes a hearing aid integrated into the external sound processor of the cochlear implant, the evidence includes prospective and retrospective studies using single-arm, within-subject comparison pre- and postintervention and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. The available evidence has suggested that a hybrid cochlear implant system is associated with improvements in hearing of speech in quiet and noise. The available evidence has also suggested that a hybrid cochlear implant improves speech recognition better than a hearing aid alone. Some studies have suggested that a shorter cochlear implant insertion depth may be associated with preserved residual low-frequency hearing, although there is uncertainty about the potential need for reoperation after hybrid cochlear implantation if there is a loss of residual hearing. Studies reporting on long-term outcomes and results of re-implantation are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
3/2022	Annual policy review. Description, summary, and references updated. Policy
	statements unchanged.
1/2022	Clarified coding information
5/2021	Policy statement on replacement of internal and/or external components solely for the purpose of upgrading to a next-generation device clarified; providers should determine the reasonable useful lifetime of the device to be five years.
4/2021	Policy statements updated to reflect expanded indications in children aged 9 months and older with profound unilateral sensorineural hearing loss. Effective 4/1/2021.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
9/2020	Annual policy review. Policy statements updated to reflect expanded indications in children aged 9 months and older with profound bilateral sensorineural hearing loss. Effective 9/1/2020.
4/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2018	Annual policy review. New references added.
1/2018	Clarified coding information.
7/2017	Annual policy review. New medically necessary and not medically necessary indications described. Clarified coding information. Effective 7/1/2017.
12/2016	Annual policy review. Policy statement changed to indicate that cochlear implantation with a hybrid cochlear implant/hearing aid system is considered medically necessary for patients meeting criteria. References added. Effective 12/1/2016.
7/2015	Annual policy review. New references added.
12/2014	Correction made to last line of the Summary.
10/2014	Annual policy review. New references added.
10/2014	Annual policy review. New investigational indications described. Coding information clarified. Effective 10/1/2014.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
1/2014	Coding information clarified. Updated to add new CPT codes 92521-92524.

12/2013	Annual policy review. New investigational indications described. Effective 12/1/2013. Coding information clarified.
5/2013	Annual policy review. New references added.
11/2011-	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No
4/2012	changes to policy statements.
12/2011	Annual policy review. Changes to policy statements.
3/2010	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
5/2009	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
3/2009	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
5/2008	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
3/2008	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
7/2007	Annual policy review. No changes to policy statements.
5/2007	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
3/2007	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use

Managed Care Guidelines

Indemnity/PPO Guidelines

Clinical Exception Process

Medical Technology Assessment Guidelines

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Endnotes

¹ Based on expert opinion