

COCHLEAR IMPLANTS

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Overview

A cochlear implant is a prosthetic device that provides a sense of sound by direct electrical stimulation of the auditory nerve. A cochlear implant has both internal and external components. The internal components are surgically implanted, and include a receiver and an electrode array. After the cochlear device is implanted, any residual hearing in the ear is most likely destroyed. The external components are fitted approximately one month after surgery, and include a microphone, sound processor, and a transmitter. A cochlear implant is also referred to as a bionic ear.

Cochlear implants are appropriate for patients with profound bilateral sensorineural hearing loss who derive little benefit from binaural hearing aids. However, cochlear implants work better for some people than others. Some people with a cochlear implant are eventually able to understand speech quite well; others may still need to rely on speech reading and sign language to communicate. Accurately predicting which patient will do well with an implant is not possible. Some factors that may affect the outcome include age of onset of deafness, age of implantation, pre-implant residual hearing, and motivation.

Individuals who receive a cochlear implant undergo an extensive pre-implantation evaluation and post-implantation programming and aural rehabilitation therapy.

Definitions

Auditory nerve – also called the eighth cranial nerve or acoustic nerve. The auditory nerve leads from the cochlea (inner ear) to the brain, serving as the pathway for the nerve impulses that the brain interprets as sound.

Binaural – when sound is presented to both ears.

Decibels (dB) – the American Speech-Language-Hearing Association and the American Academy of Audiology calculate hearing loss using decibels. To calculate hearing loss in decibels, one takes the hearing threshold at 500 Hz, 1000 Hz and 2000 Hz and averages them to derive a pure tone average. The average will fall into one of six categories: normal (< 20 dB HL), mild (20-40 dB HL), moderate (40-60 dB HL), severe (60-80 dB HL), or profound (> 80 dB HL).

Hearing threshold – the softest intensity that sound is perceived 50% of the time using pure tones.

Retrocochlear hearing loss - Retrocochlear hearing loss occurs at the level of the auditory nerve or in the auditory center of the brain. Tumors on the auditory nerve, such as vestibular schwannomas, and progressive neural disorders, such as multiple sclerosis are important causes of retrocochlear hearing loss. Certain audiologic



characteristics, such as asymmetry in the pure tone averages, speech discrimination scores, or abnormalities in advanced audiologic tests, suggest the presence of a retrocochlear lesion.

Sensorineural hearing loss – Sensorineural hearing loss results from inner ear (cochlea) or auditory nerve dysfunction. Extensive hearing testing differentiates between a sensory and a neural hearing loss, although some individuals may have both. The sensory component may be from damage to the hair cells that stimulate the auditory nerve. The neural component is a result of damage to the auditory nerve or auditory center of the brain. Neural hearing loss is also known as retrocochlear hearing loss. Sensorineural hearing loss causes a reduction in the intensity of sound and may also affect speech understanding. Sensorineural hearing loss is the most common type of hearing loss, occurring in approximately 25% of persons 65 years of age and older. Sensorineural hearing loss can also be caused by trauma, noise exposure, certain diseases, heredity, tumors and other conditions. Some types of sensorineural hearing loss can be treated medically if diagnosis is made in a timely manner. Surgery is generally not effective in treating sensorineural hearing loss. Many people with sensorineural hearing loss benefit from amplification through hearing aids.

Policy

Cochlear implants and replacement cochlear implant components require preauthorization by FCHP.

FCHP covers physician and facility¹ charges for unilateral or bilateral cochlear implants, the fitting and programming of the external components and aural rehabilitation following implantation for plan members who meet all of the following criteria:

Commercial plans

FCHP covers cochlear implants for adults 18 years of age and older who meet the all following criteria:

1. Severe to profound bilateral sensorineural deafness defined as a pure tone average hearing threshold of 70 decibels (dB) or greater at 500 Hz, 1000 Hz, and 2000 Hz.
2. Limited benefit from appropriately fitted binaural hearing aids. Limited benefit from amplification is defined by test scores of 40% correct or less in best-aided listening condition on CD recorded tests of open-set sentence recognition Hearing in Noise Test (HINT) sentences.

FCHP covers cochlear implants for children 12 months of age and older who meet all the following criteria:

1. Severe to profound bilateral sensorineural hearing loss defined as a pure tone hearing threshold of 70 dB or greater at 500 Hz, 1000 Hz and 2000 Hz.

¹ The cochlear implant system that the facility receives from the manufacturer may contain two speech processors (such as, a bodyworn model and a behind-the-ear model). FCHP covers the cost of one sound processor per cochlear implant. The second sound processor is not reimbursed by FCHP and facility should return it to the manufacturer for a refund unless the patient has specifically agreed to pay for it out-of-pocket.



2. Limited benefit from appropriately fitted binaural hearing aids.
 - a. In younger children, limited benefit is defined as lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural rehabilitation over a three-to-six month period
 - b. In older children, lack of aided benefit is defined as < 20% correct on the open-set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT) depending on the child's cognitive and linguistic skills.
 - c. For children without experience with hearing aids, a 3 to 6 month hearing aid trial must be attempted and failed. Children deafened by meningitis warrant special consideration because of the frequent complication of cochlear ossification (labyrinthitis ossificans). Because of the potential need for urgent implantation, the hearing aid trial for children deafened by meningitis may be significantly abbreviated by radiological evidence of cochlear ossification.

Fallon Senior Plan™

In accordance with the Centers for Medicare & Medicaid (CMS) National Coverage Determination (NCD) for Cochlear Implantation (50.3), FCHP covers cochlear implants for Fallon Senior Plan™ members who meet the all following criteria:

1. Moderate² to profound bilateral sensorineural deafness.
2. Limited benefit from appropriately fitted binaural hearing aids. Limited benefit from amplification is defined by test scores of 40% correct or less in best-aided listening condition on tape recorded tests of open-set sentence recognition.

In all cases, patients must be willing and capable of participating in post-implantation programming and aural rehabilitation in order to achieve benefit from the cochlear implant device.

Criteria for cochlear implantation are adapted from the FDA-approved indications for cochlear implants. Over the years, the FDA has approved many revisions and upgrades to the various components of each of these devices. Currently, there are three cochlear manufacturers in the U.S.:

- Cochlear Corporation www.cochlear.com
- MED-EL Corporation www.medel.com
- Advanced Bionics www.advancedbionics.com

Despite many similarities in cochlear implants, there are important features that distinguish them from one another. This policy is premised upon the use of FDA-approved cochlear implants in accordance with their FDA-approved indications. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm>

² CMS does not define moderate to profound hearing loss in terms of a hearing threshold in decibels. For reference, the American Speech-Language-Hearing Association defines moderate hearing loss as 40 dB to 60 dB.



Cochlear implants are contraindicated in the presence of any one or more of the following conditions:

- Retrocochlear hearing loss³, deafness due to damage to the auditory nerve or central auditory pathway
- Absence of cochlear development
- Preoperative radiographic evidence indicating cochlear ossification that would impede electrode insertion
- Tympanic membrane perforation in the presence of active middle ear disease
- Acute or chronic external or middle ear infections

Replacement of cochlear implant components not otherwise covered under a manufacturer's warranty:

There are very few mechanical problems associated with cochlear implants, and replacement of existing components due to device failure occurs infrequently. However, there have been many revisions and upgrades to the various components leading to improvements in design and speech perception. Replacement of an existing, functioning cochlear implant component is covered only when it is medically necessary, that is, when a physician certifies that:

1. The existing component is ineffective to the point of interfering with the activities of daily living, or
2. When there is a change in the patient's medical condition necessitating a different type of component, or
3. The existing component has reached its reasonable useful life. The reasonable useful life of a sound processor is not less than 5 years.

Sound processors often have a trade-in value. FCHP expects that a member will take advantage of any trade-in programs that are available when upgrading to a new model. FCHP reimbursement for a sound processor upgrade will be less any trade-in value.

Loss, theft, or accidental damage of external cochlear components, including sound processors may not be covered by the manufacturer's warranty. FCHP does not cover replace lost, stolen or damaged cochlear components.⁴ FCHP recommends that the cochlear implant wearers purchase a separate insurance policy to cover against the loss, theft, or accidental damage of their sound processor.

Cochlear implant batteries:

³ Conclusive confirmation that the hearing loss is cochlear rather than due to retrocochlear (eighth cranial nerve) or central auditory nervous system involvement, is essential before cochlear implantation is performed or even considered. Patients suspected of having retrocochlear pathology should be referred for an MRI with a gadolinium contrast.

⁴ Replacement of lost, stolen or damaged cochlear components is covered for Fallon Senior Plan™ members in accordance with Medicare regulations.



Batteries are covered only when they are the primary power source for a cochlear implant sound processor. Cochlear implant batteries are covered up to the quantity limits below. Quantity limits are per implant. Most new generation sound processors use rechargeable lithium ion batteries; whereas older model sound processors, such as the Med-EL CIS PRO+ use alkaline batteries. In some cases, sound processors may use both lithium ion and alkaline batteries interchangeably. In this situation, the quantity allowed will be adjusted accordingly.

Code	Quantity Limit Per Implant			Comments
	Per month	Per 3 months	Other	
L8621	30	90	N/A	
L8622	60	180	N/A	
L8623	N/A	N/A	4 per 12 months	
L8624	N/A	N/A	4 per 36 months	

Exclusions

1. Off-label cochlear implantation, including cochlear implants for unilateral sensorineural hearing loss or for the treatment of tinnitus in patients who do not also have severe to profound bilateral sensorineural hearing loss.
2. Replacement of lost, stolen or damaged cochlear components.
3. Replacement or upgrades of existing, functioning cochlear implants or cochlear implant components for any reason that is not medically necessary or before the component has reached its reasonable useful life. For example, upgrading to next generation, smaller profile external components, or switching from a bodyworn sound processor to a behind-the-ear model is considered not medically necessary.
4. Supplies or accessories that are not necessary for the functioning of the cochlear implant, such as cell phone adapters, telecoils, carrying cases, keychain wallets, or car charger adapters.

Codes

Surgically implanted prosthetic devices are not subject to the DME/prosthetics & orthotics benefit limit.

Codes	Number	Description
CPT	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

Codes	Number	Description
HCPCS	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, replacement
	L8621	Zinc air battery for use with cochlear implant device, 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 device speech processor, ear level, replacement, each

Products To Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Commonwealth Care
- ⊕ Companion Care
- ⊕ Fallon Senior Plan™

References

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Committee Review Dates

Benefits Committee: 04/95, 01/02

Technology Assessment Committee: 12/01, 07/10/07, 09/30/09

Utilization Management Committee: 06/03

Technology Assessment Subcommittee: 02/27/07, 03/27/07, 05/22/07, 05/07/09

IMPORTANT NOTE

Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal