Medicare Medical Policy

Cochlear Implants and Auditory Brainstem Implants

MEDICARE MEDICAL POLICY NUMBER: 189

Effective Date: 6/1/2024

Last Review Date: 5/2024

Next Annual Review: 4/2025

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners, as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Notes: This policy does not apply to osseointegrated implants (aka, bone-anchored hearing aids or BAHA), which are addressed in a separate Medicare medical policy. (See Policy Cross References below)

Service	Medicare Guidelines
Cochlear Implant(s) – Initial Provision (Standard and Hybrid Devices)	Cochlear implants for *bilateral* moderate-to-profound sensorineural hearing loss: • National Coverage Determination (NCD) for Cochlear Implantation (50.3) **NOTES:** • Medicare coverage is limited to those who demonstrate the defined criteria of bilateral sensorineural hearing loss as described in the NCD. • ***Effective 9/26/2022***, CMS may provide coverage for individuals who do not meet the NCD criteria "when performed in the context of FDA-approved category B investigational device exemption clinical trials… or as a routine cost in clinical trials under section 310.1 of the National Coverage Determinations Manual..." This would include individuals with unilateral hearing loss. • If NCD criteria are not met, and there is no indication the procedure is rendered in the context of an investigational device exemption (IDE) study or clinical trial, the service would be considered not medically necessary. • NCD coverage criteria will also be applied to hybrid cochlear implant devices.
Auditory Brainstem Implants – Initial Provision	I. Medicare considers auditory brainstem implants to be **medically necessary** when hearing aids are medically inappropriate or cannot be utilized due to congenital

	malformations, chronic disease, severe sensorineural hearing loss or surgery. II. Medicare considers auditory brainstem implants to be **not medically necessary** when the above are not met. Medicare References: • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §100 - Hearing Aids and Auditory Implants • Medicare MLN Article MM4038, *Auditory Osseointegrated and Auditory Brainstem Devices*
Replacements and Upgrades – All devices	Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §120 - Prosthetic Devices, A. General **NOTE:** I. Replacement of medically necessary **non-**functioning cochlear or auditory brainstem implants or implant components may be **medically necessary** when Medicare's prosthetic replacement requirements in the above manual are met (e.g., irreparable change in condition of device or component, etc.) and the device or required component are not under manufacturer warranty. II. Replacement or upgrades of medically necessary **functioning** cochlear or auditory brainstem implants or components may be **medically necessary** if the implant is no longer providing therapeutic benefit due to a change in the physiological condition of the member. III. Replacement or upgrades of **functioning** cochlear or auditory brainstem implants or components are **not medically necessary** when Medicare's replacement criteria are not met **OR** when the initial device didn't meet coverage criteria. This includes upgrading to next generation, smaller profile external components, or switching from a body worn sound processor to a behind-the-ear model when existing devices are still functioning and providing therapeutic benefit. These replacement or upgrade situations would be considered a "convenience." *See "Policy Guidelines" below*
Accessories	• Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.3 - Coverage of Supplies and Accessories

	• Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §90 - Payment for Additional Expenses for Deluxe Features **NOTE:** I. According to Chapter 15 of the Medicare Benefit Policy Manual, supplies or accessories used directly with a cochlear implant device to achieve the therapeutic benefit of the prosthesis or to assure the proper functioning of the device may be **medically necessary** when the base item meets medically necessary requirements. According to Chapter 20 of the Medicare Claims Processing Manual, supplies or accessories that are not necessary for the functioning of the device (e.g., cell phone adapters, telecoils, carrying cases, keychain wallets, or car charger adapters), supplies and accessories for non-covered devices, as well as accessories and upgrades to accommodate personal convenience or deluxe items are **not covered** under Medicare.
Treatment of Complications	Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare **NOTE:** Treatment of complications of implantable hearing aids may be **medically necessary** (e.g., removal due to infection) when conditions of the above Medicare manual reference are met. This includes possible coverage for the treatment of complications related to cochlear or auditory brainstem implants which did **not** meet initial placement coverage criteria.

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Bone-Anchored Hearing Aids, MP399

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

MEDICARE GENERAL COVERAGE POSITION

While hearing aids are statutorily excluded under Original Medicare, cochlear, auditory brainstem, and osseointegrated implants are all considered prosthetic devices and as such, are eligible for coverage.[1]

BACKGROUND

A cochlear implant system consists of both internal (surgically implanted) and external components.

- Internal components 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.
- External components consist of a microphone, external sound processor and a transmitter.

INITIAL IMPLANTATION, REPLACEMENT AND UPGRADES

Initial Implant

Specific Medicare coverage criteria are available for cochlear implantation within a national coverage determination (NCD).

Under Medicare, coverage is available for:

- Cochlear implantation devices and services for members with bilateral moderate-to-profound hearing loss with hearing test scores ≤40%.
- Cochlear implantation devices and all related costs for members with hearing test scores of >40% to ≤60% hearing provided in a Medicare-approved clinical trial, study, or registry. (Coverage with Evidence Development web page)
- Routine costs, but **not** for the devices themselves for members with hearing test scores >60% hearing who are in a clinical trials.[2]

With respect to auditory brainstem implants, according to Medicare:

> "Certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as prosthetic devices. **These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery**.
>
> **The following are prosthetic devices**:
>
> - Cochlear implants and **auditory brainstem implants**, i.e., devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.

- Osseointegrated implants, i.e., devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer."[1,8]

Replacement

Because cochlear implantation falls under the Medicare Benefit Category of "Prosthetic Devices," replacement of medically necessary cochlear implants and auditory brainstem implants are subject to Medicare rules for prosthetic device replacement. Specifically, documentation must demonstrate the following:

1) The initial provision of the implant device met coverage criteria; and
2) Either:
   a) A change in physiological condition of the member and their current device does not adequately provide the necessary therapeutic benefit; or
   b) There is an irreparable change in the condition of the device or part of the device; and
3) There is no warranty provision provided by the manufacturer to either replace or repair the current device.[3]

Upgrades

Items which provide features *beyond* what is necessary to support the body member would fall under the category of an "upgrade." Upgrades include "excess components" to a prosthetic or orthotic device (e.g., a feature, an accessory, or a service) that are in addition to, or more extensive and/or more expensive than, the item that is reasonable and necessary under Medicare's coverage requirements.[4] In addition, in order to be considered for coverage, Medicare requires the requested item to be both medically necessary and reasonable. This includes determining if there is a "less costly alternative" which can provide the needed and appropriate therapeutic benefit for the individual.[5]

Investigational Device Exemption (IDE) Studies and Clinical Trials

The separate Medicare medical policy for *Clinical Trials, Studies, and Registries* (MP233) provides information regarding how claims for services rendered in the context of IDE studies and clinical trials are processed by Medicare Advantage plans.

IDE Studies

Medicare approved Category B investigational device exemption studies can be found on this Medicare website.

Table 1: Medicare-Approved IDE Studies
NOTE: As of the date of this policy update, this table includes all Medicare-approved IDE studies which include the word "cochlear."

Study Title	NCT Number	IDE Number	Medicare Approval

Investigation of the FAST Sound Coding Strategy in Newly Implanted Adult Cochlear Implant Recipients	NCT02698787	G150140	9/1/2016
Implantation of the HiRes90K™ Advantage Cochlear Implant With HiFocus™ Mid-Scala and Development of a Combined Electric and Acoustic Stimulation Technology in Adults With Partial Deafness	NCT02189798	G140019	9/12/2016
Clinical Evaluation of the Cochlear Nucleus(R) CI532 Cochlear Implant in Adults	NCT03007472	G160256	5/5/2017
Cochlear Implantation in Adults With Asymmetric Hearing Loss Clinical Trial	NCT03052920	G140244	5/26/2017
MED-EL SYNCRONY Cochlear Implant System	NCT03236909	G170111	3/15/2018
Cochlear Implantation During Vestibular Schwannoma Removal or During Labyrinthectomy Surgery for Treatment of Meniere's Disease	NCT03795675	G170139	3/15/2019
Feasibility of Auditory Nerve Test System for Optimization of Simultaneous Translabyrinthine Vestibular Schwannoma Resection With Cochlear Implantation	NCT04241679	G190197	3/12/2020
Clinical Utility of Residual Hearing in the Cochlear Implant Ear	NCT04707885	G200266	2/19/2021
Cochlear Implant With Dexamethasone Eluting Electrode Array (The CI-DEX Study): Pivotal Study	NCT04750642	G200098	4/22/2021
A Pre-market, Open-label Feasibility, Prospective, Single-arm Multicenter Feasibility Investigation of Hearing Performance Using the CI632 in Adults With Low-frequency Residual Hearing	NCT04741009	G200267	5/20/2021

Clinical Trials

Services rendered in the context of a clinical trial may be eligible for coverage, but Original Medicare is the primary payer for these services. Therefore, if coverage is requested for cochlear implant procedures rendered in the context of a clinical trial, all services must be submitted to Original Medicare prior to being submitted to the Plan.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the

availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

CODING FOR AUDITORY BRAINSTEM IMPLANTS

Like all S-codes, the *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by Medicare[6], indicates HCPCS code S2235 has been assigned a Status Indicator of "I." This is defined as "Not valid for Medicare purposes." In addition, all S-codes codes, including S2235, are not recognized as valid codes for claim submission as indicated in the relevant Company coding policy *(Coding Policy 22.0 HCPCS S-Codes and H-Codes)*. Providers need to use alternate available CPT or HCPCS codes to report for the service(s) in question. According to the 2005 MLN Matters Article # MM4038, "Physicians should bill the appropriate services for implantation of the auditory brainstem device (code L8614), using the codes for tumor resection (61520, 61530, 61598), if indicated, and also a code for cranial neurostimulators (61875)."[8] However, an unlisted code may also be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level.

ACCESSORIES OR COMPONENTS

As a service covered under the Medicare Prosthetic Benefit, some accessories or components for cochlear implants may be reported using HCPCS code L9900. HCPCS L9900 is never allowed separate reimbursement because Medicare considers this code to be a bundled item or service, no matter what it is used to represent, and even if billed alone. Several LCAs and LCDs specifically call out this code as non-covered when used for specific types of devices, but the Noridian webpage for *Two New Codes Established for Miscellaneous Supplies* provides general non-coverage information, for any use.

HCPCS code L8614 includes "all internal and external components," and therefore, to report additional items with L9900 would be inappropriate coding. Some accessories or components may not be covered and reporting HCPCS code L9900 for these items would also be non-covered.

CODES*		
CPT	69930	Cochlear device implantation, with or without mastoidectomy
	69949	Unlisted procedure, inner ear
	92521	Evaluation of speech fluency (eg, stuttering, cluttering)
	92522	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria)
	92523	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)
	92524	Behavioral and qualitative analysis of voice and resonance
	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
	92640	Diagnostic analysis with programming of auditory brainstem implant, per hour
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 or auditory osseointegrated 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, each
	L8625	External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each
	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
	L9900	Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "L" code
	S2235	Implantation of auditory brainstem implant *(CMS-assigned Status "I" code – See above billing guidelines)*

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §100 - Hearing Aids and Auditory Implants
2. Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, §100.3 – Carrier Billing Procedures
3. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §40.4 - Items Covered Under Warranty
4. Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §120 - DME MACs - Billing Procedures Related To Advanced Beneficiary Notice (ABN) Upgrades
5. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.1 - Definition of Durable Medical Equipment, C. Necessary and Reasonable, 2. Reasonableness of the Equipment
6. Medicare PFS Relative Value Files web page; Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSRelative-Value-Files. Access date: 3/14/2022
7. Medicare MLN Matters Article (MM13073) for National Coverage Determination: Cochlear Implantation; Available at: https://www.cms.gov/files/document/mm13073-national-coverage-determination-cochlear-implantation.pdf
8. Medicare MLN Article MM4038, *Auditory Osseointegrated and Auditory Brainstem Devices*; Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/JA4038.pdf. [Cited 4/18/2023]

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2023	Q1 2023 code updates (converted to new format 2/2023)
7/2023	Annual review; removed decision memo and replaced with updated NCD for cochlear implant coverage, replaced Company criteria with a Medicare reference for auditory brainstem implants, added L9900 and 69949 to policy and removed L8694 from policy
11/2023	Interim updates due to new Medicare Advantage medical policy for BAHA devices
6/2024	Annual review; no criteria change