Medicare Medical Policy

Cochlear Implants and Auditory Brainstem Implants

MEDICARE MEDICAL POLICY NUMBER: 189

Effective Date: 1/1/2023

Last Review Date: 11/2022

Next Annual Review: 6/2023

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, Providence Plan Partners, and Ayin Health Solutions 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.

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 national coverage is limited to those who demonstrate the defined criteria of bilateral sensorineural hearing loss as described in the NCD. ***Prior to*** 9/26/2022, CMS left coverage of FDA-approved cochlear implants for individuals who do not meet the NCD coverage criteria to Medicare Administrative Contractors (MACs); however, ***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 as defined at 42 CFR 405.201 or as a routine cost in clinical trials under section 310.1 of the National Coverage Determinations Manual titled Routine Costs in Clinical Trials." *(*Final Decision Memo CAG-00107R*)* This includes individuals with unilateral hearing loss. • The NCD coverage criteria will also be applied to hybrid cochlear implant devices. • Finally, while Medicare considers auditory brainstem implants to be "prosthetic devices," specific coverage criteria is not available for implantation of these devices. Therefore, Company coverage criteria are used for these 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.
Auditory brainstem implants	Company medical policy for Cochlear Implants and Auditory Brainstem Implants I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met. II. These services are considered **not medically necessary** for Medicare Plan members either when the Company medical policy criteria are not met *or* when a service is deemed "investigational" by the Company policy. *Services deemed "investigational" are considered not medically necessary for Medicare Plan members.* See *Policy Guidelines below.*

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

None

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]

INITIAL IMPLANTATION, REPLACEMENT AND UPGRADES

Medicare coverage criteria are available for cochlear implantation; however, while Medicare does acknowledge auditory brainstem implants are considered "prosthetic devices," Medicare does not have specific coverage criteria available for either auditory brainstem implants.

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]

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]

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]

MEDICARE AND MEDICAL NECESSITY

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based

processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.), Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

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

BONE ANCHORED HEARING AIDS (BAHA)

HCPCS code L8690 and CPT codes 69714, 69716, 69717, 69719, 69726, 69727, 69728, 69729, and 69730 are specific to bone anchored hearing aids (BAHA), which are not addressed in this medical policy and may be considered medically necessary and covered.

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." HCPCS code S2235 is not covered by the Plan 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.

CODES*

CPT	69930	Cochlear device implantation, with or without mastoidectomy
	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, 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 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
	L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each
	S2235	Implantation of auditory brainstem implant *(Not valid for Medicare use)*

***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

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2023	Q1 2023 code updates (converted to new format 2/2023)