MEDICAL POLICY	Cochlear Implants and Auditory Brainstem Implants (Medicare Only)
Effective Date: 12/1/2022	Medical Policy Number 189
 12/1/2022	Medical Policy Committee Approved Date: 7/17; 12/17; 12/18; 4/19; 4/2020; 11/2021; 6/2022; 10/2022
Medical Officer Date	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

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").

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

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. II. 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:** I. 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 (All Lines of Business Except Medicare) 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.*

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)*

BILLING GUIDELINES

Bone Anchored Hearing Aids (BAHA)

HCPCS code L8690 and CPT codes 69714, 69716, 69717, 69719, 69726 and 69727 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.

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
Cochlear Implants	
69930	Cochlear device implantation, with or without mastoidectomy
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
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
Auditory Brainstem Implants	
92640	Diagnostic analysis with programming of auditory brainstem implant, per hour
No Prior Authorization Required	
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
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
S2235	Implantation of auditory brainstem implant *(Not valid for Medicare use)*

DESCRIPTION

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

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.

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.