



Louisiana

Auditory Brainstem Implant

Policy # 00475

Original Effective Date: 07/15/2015

Current Effective Date: 08/10/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Implantable Bone Conduction and Bone-Anchored Hearing Aids is addressed separately in medical policy 00004.

Note: Cochlear Implant is addressed separately in medical policy 00017.

Note: Semi-Implantable and Fully Implantable Middle Ear Hearing Aids is addressed separately in medical policy 00425.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider unilateral use of an auditory brainstem implant [(ABI) using surface electrodes on the cochlear nuclei] in patients with neurofibromatosis type 2 (NF2), who are 12 years of age or older, and who are rendered deaf due to bilateral resection of neurofibromas of the auditory nerve to be **eligible for coverage.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers an auditory brainstem implant (ABI) for all other conditions including non-NF2 indications is considered to be **investigational.***

Based on review of available data, the Company considers bilateral use of an auditory brainstem implant (ABI) to be **investigational.***

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Based on review of available data, the Company considers penetrating electrode auditory brainstem implant (PABI) to be **investigational**.*

Background/Overview

The auditory brainstem implant (ABI) is intended to restore some hearing in people with neurofibromatosis type 2 who are rendered deaf by bilateral removal of the characteristic neurofibromas involving the auditory nerve. The ABI consists of an externally worn speech processor that provides auditory information by electrical signal that is transferred to a receiver/stimulator implanted in the temporal bone. The receiver stimulator is, in turn, attached to an electrode array implanted on the surface of the cochlear nerve in the brainstem, thus bypassing the inner ear and auditory nerve. The electrode stimulates multiple sites on the cochlear nucleus, which is then processed normally by the brain. To place the electrode array on the surface of the cochlear nucleus, the surgeon must be able to visualize specific anatomic landmarks. Because large neurofibromas compress the brainstem and distort the underlying anatomy, it can be difficult or impossible for the surgeon to correctly place the electrode array. For this reason, patients with large, long-standing tumors may not benefit from the device.

ABIs are also being studied to determine whether they can restore hearing for other non-neurofibromatosis causes of hearing impairment in adults and children, including absence of or trauma to the cochlea or auditory nerve. It is estimated that 1.7 per 100,000 children are affected by bilateral cochlea or cochlear nerve aplasia and 2.6 per 100,000 children are affected by bilateral cochlea or cochlear nerve hypoplasia.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2000, the Nucleus®‡ 24 Auditory Brainstem Implant System (Cochlear Corp.) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. The speech processor and receiver are similar to the devices used in cochlear implants; the electrode array placed on the brainstem is the novel component of the device. The device is indicated for individuals 12 years of age or older who have been diagnosed with neurofibromatosis type 2. The Nucleus 24 Auditory Brainstem Implant System approval was based on the efficacy study of unilateral implants either at first-side or second-side tumor removal surgery.” The Nucleus 24 is now obsolete.

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In June 2016, the Nucleus ABI 541 Auditory Brainstem Implant (Cochlear Corp.) was approved by the Food and Drug Administration through a supplement to the premarket approval for the Nucleus 24. The new implant is indicated for individuals 12 years of age or older who have been diagnosed with neurofibromatosis type 2.

FDA product code: MCM.

Rationale/Source

An auditory brainstem implant (ABI) is designed to restore some hearing in people with neurofibromatosis type 2 who are rendered deaf by bilateral removal of neurofibromas involving the auditory nerve. ABIs have also been studied to restore hearing for other non-neurofibromatosis indications.

For individuals who are deaf due to bilateral resection of neurofibromas of the auditory nerve who receive an ABI, the evidence includes a large prospective case series. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. The U.S. Food and Drug Administration (FDA) approval of the Nucleus 24 device in 2000 was based on a prospective case series of 90 patients 12 years of age or older, of whom 60 had the implant for at least 3 months. From this group, 95% had a significant improvement in lip reading or improvement on sound-alone tests. While use of an ABI is associated with a very modest improvement in hearing, this level of improvement is considered significant for those patients who have no other treatment options. Based on these results, ABIs are considered appropriate for the patient population included in the trial (ie, age ≥ 12 years with NF2 and deafness following tumor removal). The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are deaf due to nontumor etiologies who receive an ABI, the evidence includes case series and systematic reviews of case series. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. In general, ABIs have not demonstrated hearing benefits over cochlear implants for many conditions not related to neurofibromatosis type 2. However, ABIs hold promise for select patients when the cochlea or cochlear nerve is absent. Many recent and ongoing ABI studies are being conducted in children. For children, hearing is critical for language development, and this device has potential to substantially improve health outcomes. The most common nontumor conditions in children are cochlear aplasia and cochlear nerve aplasia.

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There are questions about the durability of the now obsolete Nucleus 24 in active young children. Evaluation is currently ongoing with the recently available Nucleus ABI541 to determine its efficacy and durability in children. In addition, ABI studies have shown inferior outcomes in children with other disabilities. Thus, further study is also needed to define populations that would benefit from these devices. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

In 2005, National Institute Health and Care Excellence issued guidance on interventional procedures for auditory brainstem implants. The guidance stated: "...evidence on safety and efficacy of auditory brain stem implants appears adequate to support the use of this procedure by surgical teams experienced in this technique."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. The Medicare Benefit Policy Manual references hearing aids and auditory implants, stating that hearing aids are excluded from coverage, including air-conduction and bone-conduction devices. However, devices that produce the 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 used. Along with cochlear and auditory brainstem implants, the benefit manual specifically refers to osseointegrated implants as prosthetic devices.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

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Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02310399	Auditory Brainstem Implant (ABI) in Children With No Cochlear or Auditory Nerves	20	May 2020
NCT02102256	A Feasibility Study of the Placement, Use, and Safety of the Nucleus 24 Auditory Brainstem Implant in Non-Neurofibromatosis Type 2 (NF2) Pediatric Patients	10	recruitment closed
NCT02630589	Implantation of an Auditory Brainstem Implant for the Treatment of Incapacitating Unilateral Tinnitus	10	Jan 2022
NCT01864291	Study of the Nucleus 24 and ABI541 Auditory Brainstem Implant in Pediatric Non-Neurofibromatosis Type 2	15	Nov 2022
NCT01736267	Study of Nucleus 24 Auditory Brainstem Implant (ABI) in Adult Non-Neurofibromatosis Type 2 Subjects	10	Nov 2022
NCT01904448	An Early Feasibility Study of the Safety and Efficacy of the Nucleus 24 Auditory Brainstem Implant in Children With Cochlear or Cochlear Nerve Disorders Not Resulting From Neurofibromatosis Type II	10	Apr 2023
NCT02589912	Compassionate Use Arm - ABI541 Auditory Brainstem Implant for Neurofibromatosis Type 2 Patients With Deafness	10	Recruitment closed

NCT: national clinical trial.

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Policy History

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|------------|---|
| 06/25/2015 | Medical Policy Committee review |
| 07/15/2015 | Medical Policy Implementation Committee approval. New Policy |
| 06/30/2016 | Medical Policy Committee review |
| 07/20/2016 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis codes |
| 07/06/2017 | Medical Policy Committee review |

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- 07/19/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 07/05/2018 Medical Policy Committee review
- 07/11/2018 Medical Policy Implementation Committee approval. Formatting changed in the coverage section to track BCBSA's format. Coverage eligibility unchanged.
- 07/03/2019 Medical Policy Committee review
- 07/18/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 07/02/2020 Medical Policy Committee review
- 07/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2021

Coding

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	61863, 61864, 61867, 61868, 64568, 64569, 64570, 92640
HCPCS	S2235
ICD-10 Diagnosis	Q85.02

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;

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- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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