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# Auditory Brainstem Implant

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## Disclaimer

**Carefully check state regulations and/or the member contract.**
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

## Coverage

Unilateral use of an auditory brainstem implant (ABI), (using surface electrodes on the cochlear nuclei), **may be considered medically necessary** when ALL of the following criteria are met:

- Diagnosis of neurofibromatosis-type 2 (NF2); and
- The individual is 12 years of age or older; and
- The individual has been rendered deaf due to bilateral resection of neurofibromas of the auditory nerve.

An auditory brainstem implant **is considered experimental, investigational and/or unproven** for all other indications, including non-NF2 indications.

Bilateral use of an auditory brainstem implant **is considered experimental, investigational and/or unproven**.

Penetrating electrode auditory brainstem implant (PABI) **is considered experimental, investigational and/or unproven.**

## Policy Guidelines

None.

## Description

The auditory brainstem implant (ABI) is intended to restore some hearing in people with neurofibromatosis type 2 (NF2) 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. (1)

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. (2)

**Regulatory Status**

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." (1). The Nucleus® 24 is now obsolete.

In June 2016, the Nucleus ABI 541 Auditory Brainstem Implant (Cochlear Corp.) was approved by the FDA 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. (3)

FDA product code: MCM.

## Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

In the case of the auditory brainstem implant (ABI), studies that compare outcomes before and after device implantation can provide useful information on health outcomes. Following is a summary of the key literature to date.

**ABI for Bilateral Resection of Neurofibromas of the Auditory Nerve**

Clinical Context and Therapy Purpose

The purpose of an auditory brainstem implant in individuals who are deaf due to bilateral resection of neurofibromas of the auditory nerve is to provide a treatment option that is an alternative to observation alone.

The following PICO was used to select literature to inform this policy.

*Populations*

The relevant population(s) of interest are individuals who are deaf and have undergone bilateral resection of neurofibromas of the auditory nerve.

*Interventions*

The therapy being considered is an auditory brainstem implant.

*Comparators*

The following practice is currently being used to make decisions about hearing restoration in individuals who are deaf due to bilateral resection of neurofibromas of the auditory nerve: observation alone.

*Outcomes*
The general outcomes of interest are functional outcomes, quality of life and treatment-related morbidity. Functional outcomes include change in hearing and hearing-related function (e.g., sound recognition and speech perception).

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach', within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
The U.S. Food and Drug Administration (FDA) approval of the Nucleus 24 Auditory Brainstem Implant System was based on results in a case series of 90 patients with neurofibromatosis type 2 (NF2), ages 12 years and older. (1, 4) Of the 90 subjects evaluated, 28 complications occurred in 26 patients; 26 of these complications resolved without surgical or extensive medical intervention. Two patients had infections of the postoperative flap requiring explantation of the device. Sixty patients had a minimum experience of 3 to 6 months with the device, and thus effectiveness outcomes were also evaluated. Overall device benefit was defined as a significant enhancement of lip reading or an above-chance improvement on sound-alone tests. Based on this definition, 95% (57/60) of patients derived benefit from the device. Among the 90 patients receiving the implant, 16 did not receive auditory stimulation from the device postoperatively, either due to migration of the implanted electrodes or surgical misplacement.

A single small (N=10) trial from 2008 was identified on a penetrating auditory brainstem implant (PABI). (5) This prospective clinical trial enrolled patients with NF2 who received a PABI after vestibular schwannoma removal. The PABI is an extension of the ABI technology that uses surface electrodes on cochlear nuclei. The PABI uses 8 or 10 penetrating microelectrodes in conjunction with a separate array of 10 to 13 surface electrodes. The PABI met the goals of lower threshold, increased pitch range, and high selectivity, but these properties did not improve speech recognition.

A systematic review conducted by Ontario (Canada) Health as part of a Health Technology Assessment included 16 observational studies (N=491) comparing the effectiveness of ABI to no

treatment in adults with NF2 (Table 1 and Table 2). (6) Risk of bias among the included studies was assessed using the Risk of Bias in Non-randomized Studies - of Interventions (ROBINS-I) tool, and overall quality of evidence was assessed using the Grading of Recommendation, Assessment, Development and Evaluation (GRADE) Handbook. Results were reported qualitatively, and no meta-analyses were conducted due to heterogeneity in testing conditions and outcomes. The review found high quality of evidence of benefit of ABI on sound recognition (7 studies), speech perception with lip reading (5 studies) and subjective hearing benefit (5 studies). Evidence favoring ABI was moderate for speech perception without lip reading (10 studies) and low for quality of life (1 study). The most commonly reported surgical complications, based on low quality evidence from 12 studies, were cerebrospinal fluid leak in 3% to 15% of participants and infection in 10% to 13% or participants.

**Table 1. SR-MA Characteristics**

| Study | Dates | Trials | Participants | N (Range) | Design | Duration |
|---|---|---|---|---|---|---|
| Ontario Health (6) | 1993-2016; literature searches conducted through June 2018 | 19 observational studies | Adults with NF2 who were not candidates for cochlear implantation | 491 (8-61) | 6 prospective cohort studies; 11 retrospective cohort studies; 2 cross-sectional studies | 1 month to 18 years (mean, median not reported) |

SR: scientific review; MA:meta analysis; NF2: neurofibromatosis-type 2.

**Table 2. SR-MA Results**

| Study | Sound Recognition | Speech Perception | Subjective Benefits of Hearing | Quality of Life | Surgical Complications |
|---|---|---|---|---|---|
| **Ontario Health (6)** | ABI vs. no treatment | ABI vs. no treatment | ABI vs. no treatment | ABI vs. no treatment | ABI vs. no treatment |
| Number of studies; N | 7 observational studies; N=169 | 15 observational studies; N=348 | 5 observational studies; N=141 | 1 observational study; N=11 | 12 observational studies; |
| Qualitative assessment of ABI effectiveness | Allows any degree of improvement in sound recognition vs. no treatment | ABI only: Likely allows any degree of improvement in speech perception | Provides subjective benefits of hearing | May improved quality of life | Most common complications were cerebrospinal fluid leak infection |

| | | | | | |
|---|---|---|---|---|---|
| | | when used alone<br>ABI + lip reading: Allows any degree of improvement in speech perception when used in conjunction with lip-reading | | | |
| Level of evidence (GRADE) | High | ABI only: Moderate<br>ABI + lip reading: High | High | Low | Low |

SR: scientific review; MA: meta analysis; ABI: auditory brainstem implant.

Section Summary: ABI for Bilateral Resection of Neurofibromas of the Auditory Nerve

The evidence on ABI for bilateral resection of NF of the auditory nerve included large case series, a clinical trial, and a systematic review of small observational studies. A 2018 case series of 90 adults, 60 of which had the minimum experience of 3 to 6 months with the Nucleus 24 ABI system, suggested that adults may benefit from its usage. European studies followed 32 patients, 24 of which with an ABI activated experienced significant improvements on the Sound Effects Recognition Test and Monosyllable-Trochee-Polysyllable test. An Ontario (Canada) Health systematic review found ABI associated with better hearing function relative to no treatment, but evidence on other outcomes was limited.

**ABI for Nontumor Indications**

Clinical Context and Therapy Purpose

The purpose of an auditory brainstem implant in individuals who are deaf due to nontumor etiologies is to provide a treatment option that is an alternative to observation alone.

The following PICO was used to select literature to inform this policy.

*Populations*

The relevant population(s) of interest are individuals who are deaf due to nontumor etiologies.

*Interventions*

The therapy being considered is an auditory brainstem implant.

*Comparators*

The following practice is currently being used to make decisions about hearing restoration in individuals who are deaf due to nontumor etiologies: observation alone.

*Outcomes*

The general outcomes of interest are functional outcomes, quality of life and treatment-related morbidity. Functional outcomes include change in hearing and hearing-related function (eg. sound recognition and speech perception).

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

*Adults*

Merkus et al. (2014) reported on a systematic review of ABIs for non-NF2 indications. (7) Included in the review were 144 non-NF2 ABI cases from 31 articles. Non-NF2 indications for which ABIs have been evaluated include cochlear otosclerosis, temporal bone fractures, bilateral traumatic cochlear nerve disruption, autoimmune inner ear disease, auditory neuropathy, cochlear nerve aplasia, and vestibular schwannoma in the only hearing ear. Cochlear implants have generally provided in better hearing than ABIs when the cochlea and cochlear nerve are intact. Complete bilateral disruption of the cochlear nerve from trauma did not exist in the literature and cochlear malformation did not preclude cochlear implant. While the evidence is limited, it appears as if cochlear implants demonstrate greater hearing benefits than ABIs in patients with non-NF2 indications.

In a literature review by Medina et al. (2014) assessing ABI for traumatic deafness, cochlear implant performed better than ABI. (8) However, there is limited evidence on which to draw conclusions, because only 3 articles (total N=7 patients) were identified in the review on ABI for traumatic deafness.

*Children*

A systematic review of nontumor pediatric ABI outcomes was reported by Noij et al. (2015). (9) It included 21 studies with 162 children, at a mean age of 4.3 years (range, 11 months to 17 years). Nine reports were from a single group from Italy (described further below) and it could not be determined if there was patient overlap across these studies. Nearly all studies were retrospective series or cohorts; one was a case-control. Most children (63.6%) had cochlear

nerve aplasia. Other conditions were cochlear aplasia, cochlear nerve hypoplasia, cochlear malformations, ossified cochlea, auditory neuropathy, trauma, and cochlear hypoplasia. Twenty-five percent of the patients had previously received a cochlear implant. Forty major and minor implant-related complications were reported, the most common being cerebrospinal fluid (CSF) leak (8.5% of patients). The most common side effects associated with ABI use were discomfort of the body and/or limb, dizziness/vertigo/nystagmus, pain in the head and/or neck, and stimulation of the facial nerve or involuntary swallowing, gagging, or coughing. A variety of auditory tests were used; the most common (6 studies) was the Categories of Auditory Performance (CAP) index (range, 0-7; high score indicates better hearing). There was an improvement in CAP scores over time. After 5 years, almost 50% of patients had CAP scores greater than 4 (5 [understanding of common phrases without lip reading] to 7 [use of telephone with known speaker]). Children who also had nonauditory disabilities never attained a CAP score greater than 4. There was no significant effect of the age of implantation.

Many of the larger series on ABI in nontumor patients are from a group that includes Colletti and Colletti. In 2013, this group reported on ABIs in 21 children, ranging in age from 1.7 to 5 years, with deafness unrelated to neurofibromatosis, who had a poor response to cochlear implants. (10) At surgery, the cochlear nerve was absent in each patient. Significant improvements in CAP index scores were seen after ABI ($p<0.001$).

Sennaroglu et al. (2016) reported follow-up of at least 1 year on 35 children who had received ABI. (11) This followed a 2009 preliminary report of 11 prelingually deaf children ages 30 to 56 months who received an ABI. (12) Sixty children had received an ABI from this center in Turkey. The children who had received the ABI in the previous year were excluded from the 2016 analysis. Over half (n=19) of the cases were due to cochlear hypoplasia. ABI models implanted were Cochlear, Med El, and Neurelec. At regular follow-up, children were evaluated with the CAP, Speech Intelligibility Rate (SIR), Functional Auditory Performance of Cochlea Implantation (FAPCI), and Manchester scores. About half the children were in the CAP category 5 and could understand common phrases without lip reading. In the subgroup with better hearing thresholds (25-40 dB), some (17.6%) were able to understand conversation without lip reading, use the telephone with known speaker (11.8%), and follow group conversation in a noisy room (5.9%). For children with higher hearing thresholds (>50 dB), none exceeded CAP category 5. SIR and Manchester scores were also better with greater hearing thresholds. Auditory performance measured with the FAPCI was in the 10th percentile for all groups and was worse compared to cochlear implantation. As was also found in the Noij systematic review (discussed above), children with additional nonauditory disabilities had worse outcomes.

*Mixed Populations*

Other reports from the group of Colletti and Colletti include a 2005 report on ABIs in 16 children and adults who had nontumor diseases of the cochlear nerve or cochlea and 13 patients with NF2. (13) Ages ranged from 14 months to 70 years; the nontumor group included patients with head trauma, complete cochlear ossification, auditory neuropathy, and bilateral cochlear nerve aplasia. Following implantation, the adult nontumor group scored substantially higher than the patients with NF2 in open set speech perception tests. Some children showed

dramatic improvements in word and sentence recognition over a 1-year follow-up. Short-term adverse effects included dizziness or tingling sensations in the leg, arm, and throat (20/29 patients). Additional studies from this group have reported improvement in hearing with ABIs in "nontumor" patients, including a 2006 report on 54 nontumor patients (14) and a 2007 report on 22 non-neurofibromatosis patients. (15)

In a retrospective review, Colletti et al. (2010) reported on complications from ABI surgery in 83 adults and 31 children, 78 of whom had nontumor cochlear or cochlear nerve disorders. (16) Authors found that ABI complication rates were similar to those for cochlear implant surgery. Additionally, there were significantly fewer major and minor complications in nontumor patients than in NF2 patients.

Section Summary: Auditory Brainstem Implant (ABI) in Nontumor Indications

The evidence on ABI in nontumor patients includes case series and systematic reviews. A 2014 systematic review of adults suggested that ABI might improve outcomes in bilateral complete cochlear and inner ear aplasia. Recent research includes studies of children who are deaf but would not benefit from a cochlear implant. The most common conditions in these studies are cochlear aplasia and cochlear nerve aplasia. Hearing in this age group is critical for language development, and the ABI has potential to substantially improve health outcomes for this age group. However, studies of early (now obsolete) ABI devices found a high rate of failure in children and high rates of adverse events in adults. Evidence from ongoing studies assessing newer ABI models is needed to evaluate efficacy and durability in patients with nontumor ABI indications.

**Summary of Evidence**

For individuals who are deaf due to bilateral resection of neurofibromas of the auditory nerve who receive an auditory brainstem implant (ABI), the evidence includes a large prospective case series and a technology assessment that included observational studies. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. The technology assessment found the highest quality evidence for improvement in hearing function, but evidence on other outcomes was lacking. 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. A systematic review of 16 studies found that ABI was associated with improved sound recognition and speech perception. Based on these results, ABIs are considered appropriate for the patient population age ≥12 years with neurofibromatosis type 2 (NF2) and deafness following tumor removal. The evidence is sufficient to determine that the technology results in an 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, and some older (now obsolete) ABI models have been associated with high rates of device failure and adverse events in this population. In addition, ABI studies have shown inferior outcomes in children with other disabilities. However, ABIs hold promise for select patients when the cochlea or cochlear nerve is absent. Evaluation is currently ongoing with the recently available Nucleus ABI541 to determine its efficacy and durability in children. Thus, further study is needed to define populations that would benefit from these devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Practice Guidelines and Position Statements**

National Institute for Health and Care Institute

In 2005, National Institute for Clinical Excellence issued guidance on interventional procedures for ABI. (17) 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."

**Ongoing and Unpublished Clinical Trials**

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 3.

**Table 3. Summary of Key Trials**

| NCT Number | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| ***Ongoing*** | | | |
| NCT02310399 | Auditory Brainstem Implant (ABI) in Children With No Cochleae or Auditory Nerves | 20 | May 2027 |
| NCT02630589 | Implantation of an Auditory Brainstem Implant for the Treatment of Incapacitating Unilateral Tinnitus | 10 | Jan 2026 |
| ***Unpublished*** | | | |
| 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 | 5 | Oct 2017 |

NCT: national clinical trial; IRB: Institutional Review Board.

## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

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| **CPT Codes** | 61863, 61864, 61867, 61868, 92640 |
| **HCPCS Codes** | S2235 |

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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## Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

## Policy History/Revision

| Date | Description of Change |
|---|---|
| 12/15/2024 | Reviewed. No changes. |
| 01/01/2024 | Document updated with literature review. Coverage unchanged. References 5 and 6 added; others removed. |
| 04/15/2022 | Reviewed. No changes. |
| 06/15/2021 | Document updated with literature review. Coverage unchanged. References 1 and 5 added; others removed. |
| 06/15/2020 | Reviewed. No changes. |
| 10/01/2019 | Document updated with literature review. Coverage unchanged. No new references added. |
| 06/15/2018 | Reviewed. No changes. |
| 06/01/2017 | Document updated with literature review. Coverage unchanged. |
| 07/01/2016 | Reviewed. No changes. |
| 07/01/2015 | Document updated with literature review. Coverage unchanged. |
| 07/01/2014 | Reviewed. No changes. |

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|---|---|
| 02/01/2013 | Document updated with literature review. Coverage unchanged. |
| 02/15/2010 | Policy updated with literature review. Coverage statement revised as follows: Unilateral Auditory Brain Stem Implant may be considered medically necessary when stated criteria is met; bilateral auditory brain stem implant is considered experimental, investigational and unproven; Penetrating electrode auditory brainstem implant (PABI) is considered experimental, investigational and unproven. |
| 11/15/2008 | New medical document. |