7.01.83	Auditory Brainstem Implant		
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Section:	7.0 Surgery	**Page:**	Page 1 of 15

Policy Statement

I. Unilateral use of an auditory brainstem implant (ABI) (using surface electrodes on the cochlear nuclei) may be considered **medically necessary** in individuals when **all** of the following criteria are met:
   A. With neurofibromatosis type 2
   B. Who are 12 years of age or older
   C. Who are rendered deaf due to bilateral resection of neurofibromas of the auditory nerve

II. An auditory brainstem implant is considered **investigational** for all other conditions including, but not limited to the following:
   A. Non-neurofibromatosis type 2 indications
   B. Bilateral use of an auditory brainstem implant
   C. Penetrating electrode auditory brainstem implant (PABI)

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding
See the Codes table for details.

Description

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.

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 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 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.

Additional Information

Not applicable

Related Policies

- Cochlear Implant
- Implantable Bone-Conduction and Bone-Anchored Hearing Aids
- Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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

Background

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.[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,]

Literature Review

Evidence reviews 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 function¾including 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 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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.

Auditory Brainstem Implant for Bilateral Resection of Neurofibromas of the Auditory Nerve

Clinical Context and Therapy Purpose

The purpose of an ABI 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 review.

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 ABI.

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
Systematic Review
Garcia et al (2024) conducted a systematic review of published reports of ABI use.[4] A total of 36 studies were included, encompassing 662 patients with tumors and 267 patients without tumors. A study-specific scale called the Adult Pediatric Ranked Order Speech Perception (APROSPER) scale was used to assess outcomes. Among the patients with tumors, weighted mean speech recognition was 39.2% (range, 19.6% to 83.3%) for closed-set words, 23.4% (range, 17.2% to 37.5%) for open-set words, and 21.5% (range, 2.7% to 4.7%) for open-set sentences. Mean categories of auditory performance (CAP) scores were 3.1 (range, 1.0 to 3.2).

Wang et al (2024) conducted a systematic review and meta-analysis of audiological outcomes following ABI implantation in patients with neurofibromatosis type 2 schwannomatosis.[5] Among the 33 studies that were included, the pooled estimate for environmental sound discrimination was 55% (95% confidence interval [CI], 49% to 66%) and for closed set discrimination was 55% (95% CI, 40% to 69%). The pooled estimate for open-set discrimination was 30% (95% CI, 19% to 42%). Complications occurred in 33% (95% CI, 15% to 52%) of patients.

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 neurofibromatosis type 2 (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 neurofibromatosis type 2 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)

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; N=
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 when used alone ABI + lip reading: Allows any degree of improvement in speech perception when used in conjunction with lip-reading	Provides subjective benefits of hearing	May improve quality of life	Most common complications were cerebrospinal fluid leak infection
Level of evidence (GRADE)	High	ABI only: Moderate ABI + lip reading: High	High	Low	Low

Abbreviations: ABI: auditory brainstem implant.

Observational Studies

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, ages 12 years and older.[1,7,] 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 ABI (PABI)[8]. This prospective clinical trial enrolled patients with neurofibromatosis type 2 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.

Daoudi et al (2024) conducted a retrospective, single center, long term follow-up study of patients with neurofibromatosis type 2 who received an ABI.[9] Using a threshold of at least 5 years of follow-up, the investigators identified 27 patients who received a total of 32 ABIs. Mean duration of follow-up was 12 years (range, 5 to 24 years). At 1 year post-implantation, 74% of patients were still ABI users; at last follow-up, 54% of patients were still users. Hearing improvement for disyllabic words was 32% at 1 year and 41% at 5 years. Improvement in sentence recognition was 28% at 1 year and 42% at 5 years. Four patients experienced a decrease in ABI performance after 1 year, 3 of which were attributed to tumor growth.

Section Summary: Auditory Brainstem Implant for Bilateral Resection of Neurofibromas of the Auditory Nerve

The evidence on ABI for bilateral resection of neurofibromas of the auditory nerve includes large case series, small uncontrolled studies, and systematic reviews 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. A single-center study found persistent improvement after long-term (at least 5 years) follow-up. An Ontario (Canada) Health systematic review found ABI associated with better hearing function relative to no treatment, but evidence on other outcomes was limited.

Auditory Brainstem Implant for Nontumor Etiologies

Clinical Context and Therapy Purpose

The purpose of an ABI 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 review.

Populations

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

Interventions

The therapy being considered is an ABI.

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 (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

Adults

Merkus et al (2014) conducted a systematic review of ABIs for non-neurofibromatosis type 2 indications.[10,] Included in the review were 144 non-neurofibromatosis type 2 ABI cases from 31 articles. Non-neurofibromatosis type 2 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 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-neurofibromatosis type 2 indications.

In a literature review by Medina et al (2014) assessing ABI for traumatic deafness, cochlear implant performed better than ABI.[11,] However, there was 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

Sennaroglu et al (2024) published a summary of outcomes reported by institutions that participated in the Third International Pediatric ABI Meeting on pediatric ABI implantation in inner ear malformations.[12,] After cases from all participating institutions were described, the experts concluded that early implantation (before age 3 years) correlates with better auditory and language development, and that auditory outcomes after ABI implantation are diverse because of individual anatomic and developmental factors. Decision-making should be individualized and include consideration of patient appropriateness for surgery and access to rehabilitation services. The authors also concluded that outcomes in children with normal anatomy who receive an ABI are not as strong as children who receive cochlear implant, so ABI is mainly considered in patients who are not candidates for cochlear implants (e.g., patients with complex inner ear malformation or a dysplastic cochlear nerve). The authors hope that these conclusions will inform a future consensus statement.

Systematic Reviews

The Garcia et al (2024) systematic review previously described included 267 patients without tumors.[4,] Among these patients, weighted mean speech recognition was 79.8% (range, 31.7% to 84.4%) for closed-set words and 53.0% (range, 14.6% to 72.5%) for open-set sentences. Mean CAP scores were 2.30 (range, 2.0 to 4.7).

A systematic review of nontumor pediatric ABI outcomes was reported by Noij et al (2015).[13,] 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 below) and it could not be determined if there was patient overlap across these studies. Nearly all studies were retrospective series or cohorts; 1 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 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 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.

Case Series

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.[14] At surgery, the cochlear nerve was absent in each patient. Significant improvements in CAP index scores were seen after ABI ($p<.001$).

Sennaroglu et al (2016) reported on follow-up of at least 1 year for 35 children who had received ABI.[15] This followed a 2009 preliminary report of 11 prelingually deaf children ages 30 to 56 months who received an ABI.[16] 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, Functional Auditory Performance of Cochlea Implantation, 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 decibels), 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 decibels), none exceeded CAP category 5. Speech Intelligibility Rate and Manchester scores were also better with greater hearing thresholds. Auditory performance measured with the Functional Auditory Performance of Cochlea Implantation was in the 10th percentile for all groups and was worse compared with cochlear implantation. As was also found in the Noij systematic review (discussed above), children with additional nonauditory disabilities had worse outcomes.

Bas et al (2024) reported on sensory processing, attention, and memory in 25 children with ABIs.[17] Patient age ranged from 6 to 10 years. The patients were stratified by duration of use, with 12 children having a mean duration of 63.25 months and 13 children having a duration of 76.38 months. The group with a longer duration of ABI use had higher attention and short-term memory performance as measured by the visual-aural digit span test B, better visual and spatial perception as measured by the Marking Test (all $p<.05$).

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 neurofibromatosis type 2.[18] 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 events included dizziness or tingling sensations in the leg, arm, and throat (20/29 patients). Additional studies from this group have reported improvements in hearing with ABIs in "nontumor" patients, including a 2006 report on 54 nontumor patients[19,] and a 2007 report on 22 non-neurofibromatosis patients.[20,]

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.[21,] 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 neurofibromatosis type 2 patients.

Section Summary: Auditory Brainstem Implant in Nontumor Etiologies

The evidence on ABI in nontumor patients includes case series and systematic reviews. A 2014 systematic review 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.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Institute for Health and Care Excellence

In 2005, the National Institute for Health and Care Excellence issued guidance on interventional procedures for auditory brainstem implants.[22,] 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 3.

Table 3. Summary of Key Trials

	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05810220	Investigating Auditory Processing in the Users of Auditory Brainstem and Cochlear Implants	200	Dec 2026
NCT02630589	Implantation of an Auditory Brainstem Implant for the Treatment of Incapacitating Unilateral Tinnitus	10	Jan 2028
NCT02310399	Auditory Brainstem Implant (ABI) in Children With No Cochlear or Auditory Nerves	20	May 2030

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

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22. National Institute Health and Care Excellence (NICE). Auditory brain stem implants [IPG108]. 2005 https://www.nice.org.uk/guidance/ipg108. Accessed December 31, 2024.

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
- Previous treatment plan and response
- Age and diagnosis of neurofibromatosis
- Previous applicable procedures and results
- Hearing test results, if applicable
- Brainstem implant manufacturer and model

For Upgrade or Replacement

- Manufacturer warranty information, description of non-function or failure, repair log, and reason component or system cannot be repaired (if applicable)
- Treating provider's progress notes indicating:
    - Type of present device and length of usage
    - Patient's current condition and change in condition (if applicable)
    - Inadequacies of the present system or component
    - Patient's capabilities with his/her current implant and of the requested upgrade or component (if applicable)
    - How the upgrade or component is expected to provide clinically significant improvement (if applicable)

Post Service (in addition to the above, please include the following):

- Operative/procedures notes (if applicable)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	61863	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
	61864	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
	61867	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array
	61868	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
	64568	Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
	92640	Diagnostic analysis with programming of auditory brainstem implant, per hour
HCPCS	S2235	Implantation of auditory brain stem implant

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/31/2015	BCBSA Medical Policy adoption
01/01/2016	Coding Update
11/01/2016	Policy revision without position change
04/01/2017	Policy revision without position change
04/01/2018	Policy revision without position change

Effective Date	Action
04/01/2019	Policy revision without position change
04/01/2020	Annual review. Policy statement and literature updated.
04/01/2021	Annual review. No change to policy statement. Literature review updated.
03/01/2022	Coding update.
04/01/2022	Annual review. No change to policy statement. Literature review updated.
04/01/2023	Annual review. Policy statement and Literature review updated.
04/01/2024	Annual review. Policy statement and literature updated.
04/01/2025	Annual review. No change to policy statement. Policy guidelines and literature updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

<table>
<tr><th colspan="2">POLICY STATEMENT
(No changes)</th></tr>
<tr><th>BEFORE</th><th>AFTER</th></tr>
<tr><td>Auditory Brainstem Implant 7.01.83

Policy Statement:
I. Unilateral use of an auditory brainstem implant (ABI) (using surface electrodes on the cochlear nuclei) may be considered medically necessary in individuals when all of the following criteria are met:
A. With neurofibromatosis type 2
B. Who are 12 years of age or older
C. Who are rendered deaf due to bilateral resection of neurofibromas of the auditory nerve

II. An auditory brainstem implant is considered investigational for all other conditions including, but not limited to the following:
A. Non-neurofibromatosis type 2 indications
B. Bilateral use of an auditory brainstem implant
C. Penetrating electrode auditory brainstem implant (PABI)</td><td>Auditory Brainstem Implant 7.01.83

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</table>