



# Louisiana

## Auditory Brainstem Implant

**Policy #** 00475

Original Effective Date: 07/15/2015

Current Effective Date: 07/11/2018

*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 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 ABI to be **investigational**.\*

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

### **Background/Overview**

The ABI is intended to restore some hearing in people with 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

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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<sup>®</sup> 24 Auditory Brainstem Implant System (Cochlear Corp.) was approved by the U.S. 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 NF2. 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.

In June 2016, the Nucleus ABI541 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 NF2.

FDA product code: MCM.

#### **Centers for Medicare and Medicaid Services (CMS)**

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 ABIs, the benefit manual specifically refers to osseointegrated implants as prosthetic devices.

### **Rationale/Source**

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 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.

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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.

In the case of the 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**

The U.S. FDA approval of the Nucleus 24 Auditory Brainstem Implant System was based on results in a case series of 90 patients with NF2, ages 12 years and older. 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.

Similar results have been reported with other devices in European studies. Matthies et al (2013) reported on 32 patients with ABIs placed for NF2. Activation of the ABI occurred in 27 patients. Three patients experienced no auditory perception. At 12-month follow-up, significant improvements were seen on the Sound Effects Recognition Test and the Monosyllable-Trochee-Polysyllable test. Open set sentence recognition was 5% at first fitting and improved to 37% at 12 months. Performance did not significantly correlate with the number of active electrodes implanted. Sanna et al (2012) reported on 25 ABIs placed in 24 patients with NF2. In this retrospective case study, patients were followed for 2 to 53 months. Sound recognition was present in 19 patients, of whom 11 had some word recognition and 8 had good speech recognition (50% speech discrimination in 4 patients, 75%-100% speech discrimination and telephone use in 4 patients). Multivariate analysis failed to identify any statistically significant factors that predicted ABI performance outcomes. The authors also conducted a review of the literature on ABIs and found it difficult to compare outcomes because reporting methods and outcomes measured were inconsistent and imprecise.

A single small (N=10) trial from 2008 was identified on a PABI. 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

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of lower threshold, increased pitch range, and high selectivity, but these properties did not improve speech recognition.

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

The largest dataset on use of the ABI in patients with NF2 is from the FDA-regulated prospective series with the Nucleus 24 implant. This study found enhancement of lip reading and improvement in sound-alone tests in patients who had bilateral deafness and no sound perception prior to the ABI. Eighteen percent of patients did not receive auditory benefit after device implantation. Based on these results, FDA approved the Nucleus 24 implant for the indications in the trial (patients  $\geq 12$  years with NF2). Similar results have been shown in smaller retrospective series from Europe in patients with NF2. No benefit on speech recognition was found with penetrating electrodes compared with surface electrodes.

### **ABI FOR NONTUMOR INDICATIONS**

#### **Adults**

Merkus et al (2014) reported on a systematic review of ABIs for non-NF2 indications. 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 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. 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**

##### **Systematic Reviews**

A systematic review of nontumor pediatric ABI outcomes was reported by Noij et al (2015). 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; 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 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

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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. 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 on follow-up of at least 1 year for 35 children who had received ABI. This followed a 2009 preliminary report of 11 prelingually deaf children ages 30 to 56 months who received an ABI. 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 handicaps had worse outcomes (e.g., intellectual disability).

Also, Puram et al (2016) reported on early experiences with pediatric ABI in a North American center conducting an ongoing FDA-regulated investigational device exemption trial (NCT01864291). Of 17 candidates evaluated, 5 (average age, 19.2 months) met the study selection criteria and received an implant (Nucleus AB124). Detailed inclusion and exclusion criteria are described in the report. The age at implantation ranged from 11 months to 2.5 years. After implantation, all patients had responses such as babbling and responses to sounds and speech. There were no major or minor complications such as cerebrospinal fluid leak. Two devices failed after blunt trauma (falls) at 6 and 7 months postimplantation, respectively, and 1 spontaneous device failure occurred at 15 months postsurgery. The current protocol includes use of a helmet in children who are at risk of falling.

### **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. 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

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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 and a 2007 report on 22 non-neurofibromatosis patients.

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. 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: ABI in Nontumor Indications**

The evidence on ABI in nontumor patients includes case series and systematic reviews of case series. 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, a 2016 U.S. study found a high rate of device failure (3/17) with the only device approved for use in the United States (now obsolete), and other studies have indicated that outcomes are inferior when children have additional disabilities. A number of studies in children are ongoing (see Table 1). Results from these studies might identify the patient populations who would benefit most from this device. Results on the recently available Nucleus AB124 are also needed to evaluate device efficacy and durability.

### **SUMMARY OF EVIDENCE**

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 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 (i.e., age  $\geq 12$  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 NF2. 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

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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. 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.

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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  
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.  
Next Scheduled Review Date: 07/2019

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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:

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- 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;
- 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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