Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Auditory Brain Stem Implant

Description/Background

The auditory brain 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 to an electrical signal that is transferred to a receiver/stimulator that is implanted in the temporal bone. The receiver stimulator is, in turn, attached to an electrode array that is 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

One device has received approval by the U.S. Food and Drug Administration (FDA) for auditory brainstem implantation: the Nucleus 24® Auditory Brainstem Implant System (Cochlear Corporation). 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 (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."[2] The Nucleus® 24 is now obsolete.

In June 2016, the Nucleus ABI541 Auditory Brainstem Implant (Cochlear Corp.) was approved by 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.

FDA product code: MCM.

Medical Policy Statement

The safety and effectiveness of unilateral auditory brain stem implantation have been established. It may be considered a useful therapeutic option for patients meeting selection criteria.

Inclusionary and Exclusionary Guidelines

Inclusions: (must meet both):

- At least 12 years of age or older who have neurofibromatosis Type II **AND**
- Who are rendered deaf due to bilateral resection of neurofibromas of the auditory nerve.

Exclusions:

- Use of an auditory brain stem implant for all other conditions, including, but not limited to, the use of ABI for children with cochlear nerve deficiency, aplasia or malformation.
- Bilateral use of an ABI who otherwise meet criteria for ABI.
- Penetrating electrode auditory brainstem implant (PABI)

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

S2235

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

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.

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.

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 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 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
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. A total of 60 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, a total of 95% patients (57 of 60) derived benefit from the device. While the use of an auditory brainstem implant (ABI) is associated with a very modest improvement in hearing, this level of improvement is considered significant in this group of patients who have no other treatment options. 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).[7] 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).[5] 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	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)

Table 2. SR-MA Results

Study	Sound Recognition	Speech Perception	Subjective Benefits of Hearing	Quality of Life	Surgical Complications
Ontario Health[5]	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

Section Summary: ABI for Bilateral Resection of Neurofibromas of the Auditory Nerve
The evidence on ABI for bilateral resection of neurofibromas of the auditory nerve includes case series, literature reviews and 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 ETIOLOGIES

Review of Evidence

Adults
Merkus et al (2014) conducted a systematic review of ABIs for non-NF2 indications in 2014.[6] Included in the review were 144 non-NF2 ABI cases from 31 articles. Non-NF2 indications for which ABIs have been evaluated included cochlear otosclerosis, temporal bone fractures, bilateral traumatic cochlear nerve disruption, autoimmune inner ear disease, auditory neuropathy, cochlear nerve aplasia and when vestibular schwannoma is in the only hearing ear. Cochlear implants generally resulted in better hearing than ABIs when the cochlea and cochlear nerve were 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 cochlear implants demonstrate greater hearing benefits than ABI in patients with non-NF2 indications.

In a 2014 systematic review by Medina et al of ABI for traumatic deafness, cochlear implant was found to perform better than ABI.[7] However, there is limited evidence available to draw conclusions, because only 3 articles totaling 7 patients were identified in the review on ABI for traumatic deafness.

Children

Systematic Reviews
A 2015 systematic review of nontumor pediatric ABI outcomes was reported by Noij et al (2015).[8] 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.

Case Series

Many of the larger series on ABI in nontumor patients are from a group that includes Collettti and Colletti. In 2013, L. Colletti reported on ABIs in 21 children, ranging in age from 1.7 to 5 years, with deafness unrelated to neurofibromatosis, which had a poor response to cochlear implants.[9] At surgery, the cochlear nerve was absent in each patient. Significant improvement in Category of Auditory Performance scale was seen after ABI ($p<0.001$).

In 2016, Sennaroglu et al reported follow-up of at least 1 year on 35 children who had received ABI.[10] This followed a 2009 preliminary report of 11 prelingually deaf children ages 30 to 56 months who received an ABI.[11] 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 handicaps had worse outcomes (e.g., intellectual disability).

Mixed Populations

Other reports from the group of Colletti and Colletti include a 2005 report on ABIs in 16 children and adults who had non-tumor diseases of the cochlear nerve or cochlea and 13 patients with NF2.[12] Ages ranged from 14 months to 70 years; the non-tumor group included patients with head trauma, complete cochlear ossification, 1 child with auditory neuropathy, and 5 children with bilateral cochlear nerve aplasia. Following implantation, the adult non-tumor group scored substantially higher than the patients with NF2 in open set speech perception tests. Some of the 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 of 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[13] and a 2007 report on 22 non-neurofibromatosis patients.[14]

In a 2010 retrospective review, Colletti et al, reported on the complications from ABI surgery in 83 adults and 31 children, 78 of whom had nontumor cochlear or cochlear nerve disorders.[15] The authors found complication rates were similar to cochlear implant surgery. Additionally, major and minor complications were significantly fewer in nontumor patients than in NF2

patients. These authors concluded ABIs could be used in a wider population of patients than only those with NF2.

Section Summary: ABI in Nontumor Etiologies
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, 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 (Table 3).

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. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. The U.S. Food and Drug Administration (FDA) approval of the Nucleus 24 device in 2000 was based on a prospective case series of 90 patients 12 years of age or older, of whom 60 had the implant for at least 3 months. From this group, 95% had a significant improvement in lip reading or improvement on sound-alone tests. While use of an ABI is associated with a very modest improvement in hearing, this level of improvement is considered significant for those patients who have no other treatment options. 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 NF2 and deafness following tumor removal. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. 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 non-NF2 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 ABI541to 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.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

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

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02310399	Auditory brainstem implant (ABI) in children with no chochleae or auditory nerves	20	May 2027
NCT02630589	Implantation of an auditory brainstem implant for the treatment of incapacitating unilateral tinnitus	10	Jan 2026
NCT05810220	Investigating Auditory Processing in the Users of Auditory Brainstem andCochlear Implants	200	Dec 2026
Unpublished			
NCT01736267	Study of nucleus 24 auditory brainstem implant (ABI) in adult non-neurofibromatosis type 2 subjects	10	Nov 2022
NCT01904448	An early feasibility study of the safety and efficacy of the nucleus 24 auditory brainstem implant in children with cochlear or cochlear nerve disorders not resulting from neurofibromatosis type II	10	Oct 2017

NCT: national clinical trial

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Institute for Clinical Excellence (NICE)

In January 2005, National Institute for Clinical Excellence (NICE) issued Interventional Procedure Guidance 108, *Auditory Brain Stem Implants*.[16] The guidance states the following: "…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."

Government Regulations

National:

CMS Manual System Pub 100-02 – Medicare Benefit Policy, Chapter 15. Revision 12532. Issued: 03/07/2024)

Section 1862(a)(7) of the Social Security Act states that no payment may be made under part A or part B for any expenses incurred for items or services "where such expenses are for . . . hearing aids or examinations therefore. . . ." This policy is further reiterated at 42 CFR 411.15(d) which specifically states that "hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids" are excluded from coverage. Hearing aids are amplifying devices that compensate for impaired hearing. Hearing aids include air conduction devices that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

Certain devices that produce 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 utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.

The following are prosthetic devices:

- Cochlear implants and auditory brainstem implants, i.e., devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.
- Osseointegrated implants, i.e., devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer.

Medicare contractors deny payment for an item or service that is associated with any hearing aid as defined above. See §180 for policy for the medically necessary treatment of complications of implantable hearing aids, such as medically necessary removals of implantable hearing aids due to infection.[20]

Local:

There is no local coverage determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Bone Anchored Hearing Devices
- Cochlear Implants
- Intraoral Bone Conduction Hearing Devices

References

1. Food and Drug Administration. Nucleus 24 Auditory Brainstem Implant System. FDA summary of Safety and Effectiveness. 2000; https://www.accessdata.fda.gov/cdrh_docs/pdf-Poooo15B.pdf. Accessed June 2024.
2. Kaplan AB, Kozin ED, Puram SV, et al. Auditory brainstem implant candidacy in the United States in children 0-17 years old. Int J Pediatr Otorhinolaryngol. Mar 2015;79(3):310-315. PMID 25577282
3. Food and Drug Administration. Premarket Approval (PMA). Nucleus AB1541 Auditory Brainstem Implant. 2016. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000015S012. Accessed June 2024.
4. Ebinger K, Otto S, Arcaroli J, et al. Multichannel auditory brainstem implant: US clinical trial results. J Laryngol Otol Suppl. 2000(27):50-53. PMID 11211440
5. Ontario Health (Quality). Auditory brainstem implantation for adults with neurofibromatosis 2 or severe inner ear abnormalities: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2020 Mar;20(4): 185. https://www.hqontario.ca/evidence-to-improve-

care/health-technology- assessment/reviews-and-recommendations/auditory-brainstem-implantation-for-adults-with- neurofibromatosis-2-or-severe-inner-ear-abnormalities. Accessed June 2024.
6. Merkus P, Di Lella F, Di Trapani G, et al. Indications and contraindications of auditory brainstem implants: systematic review and illustrative cases. Eur Arch Otorhinolaryngol. Jan 2014;271(1):3-13. PMID 23404468
7. Medina M, Di Lella F, Di Trapani G, et al. Cochlear implantation versus auditory brainstem implantation in bilateral total deafness after head trauma: personal experience and review of the literature. Otol Neurotol. Feb 2014;35(2):260-270. PMID 24448286
8. Noij KS, Kozin ED, Sethi R, et al. Systematic review of nontumor pediatric auditory brainstem implant outcomes. Otolaryngol Head Neck Surg. Nov 2015;153(5):739-750. PMID 26227469
9. Colletti L, Wilkinson EP, Colletti V. Auditory brainstem implantation after unsuccessful cochlear implantation of children with clinical diagnosis of cochlear nerve deficiency. Ann Otol Rhinol Laryngol. Oct 2013;122(10):605-612. PMID 24294682
10. Sennaroglu L, Sennaroglu G, Yucel E, et al. Long-term results of ABI in children with severe inner ear malformations. Otol Neurotol. Aug 2016;37(7):865-872. PMID 27273392
11. Sennaroglu L, Ziyal I, Atas A, et al. Preliminary results of auditory brainstem implantation in prelingually deaf children with inner ear malformations including severe stenosis of the cochlear aperture and aplasia of the cochlear nerve. Otol Neurotol. Sep 2009;30(6):708-715. PMID 19704357
12. Colletti V, Carner M, Miorelli V, et al. Auditory brainstem implant (ABI): new frontiers in adults and children. Otolaryngol Head Neck Surg. Jul 2005;133(1):126-138. PMID 16025066
13. Colletti V. Auditory outcomes in tumor vs. nontumor patients fitted with auditory brainstem implants. Adv Otorhinolaryngol. 2006;64:167-185. PMID 16891842
14. Colletti L. Beneficial auditory and cognitive effects of auditory brainstem implantation in children. Acta Otolaryngol. Sep 2007;127(9):943-946. PMID 17712673
15. Colletti V, Shannon RV, Carner M, et al. Complications in auditory brainstem implant surgery in adults and children. Otol Neurotol. Jun 2010;31(4):558-564. PMID 20393378
16. National Institute for Clinical Excellence (NICE). NICE Interventional Procedure Guidance [IPG108]. Auditory brain stem implants. 2005 January; https://www.nice.org.uk/guidance/ipg108. Accessed June 2024.
17. CMS Medicare Policy Benefit Manual. Chapter 16, Section 100 - Hearing Aids and Auditory Implants. (Rev. 39; Issued: 11-10-05; Effective: 11-10-05; Implementation: 12-12-05). Available at http://www.cms.gov/manuals/Downloads/bp102c16.pdf (accessed June 2024).
18. Blue Cross Blue Shield Association. Auditory Brainstem Implant – Archived. Medical Policy Reference Manual. Policy #7.01.83, Issue 3:2015, original policy date 7/12/02, last review date March 2024.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
6/16/03	6/10/03	6/16/03	Joint policy established
6/15/05	6/15/05	5/20/05	Scheduled review of established policy. Policy retired.
5/1/14	2/18/14	3/3/14	Policy taken out of retirement due to requests for ABI surgery for non-FDA approved indications.
1/1/16	10/13/15	10/27/15	Routine maintenance
11/1/16	8/16/16	8/16/16	Routine maintenance, no changes in policy statement.
11/1/17	8/15/17	8/15/17	Updated rationale section. Added reference# 9 and 11-13. No change in policy status.
11/1/18	8/21/18	8/21/18	Routine maintenance. No changes in policy statement.
11/1/19	8/20/19		Routine maintenance. No change in policy statement.
11/1/20	8/18/20		Routine policy maintenance. No change in policy statement.
11/1/21	8/17/21		Routine policy maintenance. No change in policy status.
11/1/22	8/16/22		Routine policy maintenance, no change in policy status.
11/1/23	8/15/23		Routine policy maintenance, no change in policy status. Vendor managed: N/A (ds)
11/1/24	8/20/24		Routine policy maintenance, no change in status. Vendor managed: N/A (ds)

Next Review Date: 3rd Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: AUDITORY BRAIN STEM IMPLANT

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.