



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an independent
Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Auditory Brainstem Implant

Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

Policy Number: 481

BCBSA Reference Number: 7.01.83 (For Plans internal use only)
NCD/LCD: N/A

Related Policies

- Cochlear Implant, #[478](#)
- Implantable Bone-Conduction and Bone-Anchored Hearing Aids, #[479](#)
- Semi-Implantable and Fully Implantable Middle Ear Hearing Aid, #[480](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Unilateral use of an auditory brainstem implant (using surface electrodes on the cochlear nuclei) may be **MEDICALLY NECESSARY** in individuals with neurofibromatosis type 2, who are 12 years of age or older, and who are rendered deaf due to bilateral resection of neurofibromas of the auditory nerve.

An auditory brainstem implant is **INVESTIGATIONAL** for all other conditions including non-neurofibromatosis-type 2 indications.

Bilateral use of an auditory brainstem implant is **INVESTIGATIONAL**.

Penetrating electrode auditory brainstem implant (PABI) is **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue SM	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

CPT codes:	Code Description
92640	Diagnostic analysis with programming of auditory brainstem implant, per hour

HCPCS Codes

HCPCS codes:	Code Description
S2235	Implantation of auditory brain stem implant

ICD-10 Diagnosis Codes

ICD-10 diagnosis codes:	Code Description
Q85.02	Neurofibromatosis, type 2

Description

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

Summary

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 auditory brainstem implant (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.

Policy History

Date	Action
4/2024	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2023	Annual policy review. Minor editorial refinements to policy statements; intent unchanged.
3/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2016	Annual policy review. New references added.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
5/2014	Annual policy review. New references added.
5/2013	Annual policy review. New references added.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Annual policy review. Changes to policy statements.
7/2010	Updated 7/10 based on the review of the BCBSA policy. Changes to policy statement.
5/2010	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.

3/2010	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
5/2009	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
3/2009	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
1/2009	Annual policy review. No changes to policy statements.
5/2008	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
5/2008	Annual policy review. No changes to policy statements.
3/2008	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
7/2007	Annual policy review. No changes to policy statements.
5/2007	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
3/2007	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
3/2007	Annual policy review. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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/P000015B.pdf; Accessed January 20, 2023.
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 ABI541 Auditory Brainstem Implant. 2016. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000015S012>. Accessed January 19, 2023.
4. Ebinger K, Otto S, Arcaroli J, et al. Multichannel auditory brainstem implant: US clinical trial results. *J Laryngol Otol Suppl*. 2000; (27): 50-3. PMID 11211440
5. Otto SR, Shannon RV, Wilkinson EP, et al. Audiologic outcomes with the penetrating electrode auditory brainstem implant. *Otol Neurotol*. Dec 2008; 29(8): 1147-54. PMID 18931643
6. 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 February 2, 2023.
7. 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
8. 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): 260-70. PMID 24448286
9. 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): 739-50. PMID 26227469

10. 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): 605-12. PMID 24294682
11. Sennaroğlu L, Sennaroğlu G, Yücel E, et al. Long-term Results of ABI in Children With Severe Inner Ear Malformations. *Otol Neurotol*. Aug 2016; 37(7): 865-72. PMID 27273392
12. 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): 708-15. PMID 19704357
13. 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): 126-38. PMID 16025066
14. Colletti V. Auditory outcomes in tumor vs. nontumor patients fitted with auditory brainstem implants. *Adv Otorhinolaryngol*. 2006; 64: 167-185. PMID 16891842
15. Colletti L. Beneficial auditory and cognitive effects of auditory brainstem implantation in children. *Acta Otolaryngol*. Sep 2007; 127(9): 943-6. PMID 17712673
16. Colletti V, Shannon RV, Carner M, et al. Complications in auditory brainstem implant surgery in adults and children. *Otol Neurotol*. Jun 2010; 31(4): 558-64. PMID 20393378
17. National Institute Health and Care Excellence (NICE). Auditory brain stem implants [IPG108]. 2005 <https://www.nice.org.uk/guidance/ipg108>. Accessed February 2, 2023.