MASSACHUSETTS

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Medical Policy

Auditory Brainstem Implant

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Policy Number: 481

BCBSA Reference Number: 7.01.83
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 Blue[SM] and Medicare PPO Blue[SM] Members

Unilateral use of an auditory brainstem implant (using surface electrodes on the cochlear nuclei) may be **MEDICALLY NECESSARY** in patients 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℠	Prior authorization is **not required**.
Medicare PPO Blue℠	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

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.

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 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. Based on these results, ABIs are considered appropriate for the patient population included in the trial (ie, age ≥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 neurofibromatosis type 2. 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 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.

Policy History

Date	Action
4/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
4/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statement(s) unchanged.
10/2016	New references added from BCBSA National medical policy.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
5/2014	New references from BCBSA National medical policy.
5/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	BCBSA National medical 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	BCBSA National medical policy review. No changes to policy statements.
5/2008	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
5/2008	BCBSA National medical policy review. No changes to policy statements.

3/2008	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
7/2007	BCBSA National medical 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	BCBSA National medical policy review. 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 February 4, 2020.
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 December 22, 2019.
4. Ebinger K, Otto S, Arcaroli J, et al. Multichannel auditory brainstem implant: US clinical trial results. J Laryngol Otol Suppl. Feb 2000(27):50-53. PMID 11211440
5. Matthies C, Brill S, Kaga K, et al. Auditory brainstem implantation improves speech recognition in neurofibromatosis type II patients. ORL J Otorhinolaryngol Relat Spec. Sep 2013;75(5):282-295. PMID 24042846
6. Sanna M, Di Lella F, Guida M, et al. Auditory brainstem implants in NF2 patients: results and review of the literature. Otol Neurotol. Feb 2012;33(2):154-164. PMID 22246383
7. Otto SR, Shannon RV, Wilkinson EP et al. Audiologic outcomes with the penetrating electrode auditory brainstem implant. Otol. Neurotol. 2008 Dec;29(8). PMID 18931643
8. 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
9. 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
10. 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
11. 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
12. 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
13. 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
14. Puram SV, Barber SR, Kozin ED, et al. Outcomes following pediatric auditory brainstem implant surgery: early experiences in a North American center. Otolaryngol Head Neck Surg. Jul 2016;155(1):133-138. PMID 27095049

15. 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
16. Colletti V. Auditory outcomes in tumor vs. nontumor patients fitted with auditory brainstem implants. Adv Otorhinolaryngol. Aug 2006;64:167-185. PMID 16891842
17. Colletti L. Beneficial auditory and cognitive effects of auditory brainstem implantation in children. Acta Otolaryngol. Sep 2007;127(9):943-946. PMID 17712673
18. 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
19. National Institute Health and Care Excellence (NICE). Auditory brain stem implants [IPG108]. 2005 https://www.nice.org.uk/guidance/ipg108. Accessed January 19, 2018.
20. Centers for Medicare & Medicaid Services. Medicare Policy Benefit Manual. Chapter 16 - General Exclusions from Coverage. 2014; http://www.cms.gov/manuals/Downloads/bp102c16.pdf. Accessed January 19, 2020.