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# MEDICAL POLICY – 7.01.83 Auditory Brainstem Implant

BCBSA Ref. Policy:	7.01.83		
Effective Date:	May 1, 2025	RELATED I	MEDICAL POLICIES:
Last Revised:	Apr. 7, 2025	7.01.84	Semi-Implantable and Fully Implantable Middle Ear Hearing Aids
Replaces:	N/A	7.01.547	Implantable Bone Conduction and Bone-Anchored Hearing Aids
		7.01.586	Cochlear Implant

# Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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# Introduction

Neurofibromatosis type 2 is an inherited condition. It causes noncancerous tumors to grow on nerves. The usual location of these tumors is on the auditory nerves. These nerves transmit information from the inner ear to the brain and allow us to hear. Removing neurofibromatosis type 2 tumors can damage the auditory nerve, leading to deafness. An auditory brainstem implant is a device that transmits sound directly to the brainstem. The implant has two parts: the processor, which is worn near the ear, and a surgically implanted electrode. A microphone picks up sound and the processor turns the sound waves into electrical signals. The electrical signals are sent to an electrode near the brain stem. Medical studies show that auditory brainstem implants are successful in people whose hearing was damaged by surgery to remove tumors that were specifically caused by neurofibromatosis type 2. Using auditory brainstem implants has also been proposed to treat deafness from other types of tumors or other conditions. More studies are needed to see if auditory brainstem implants work for conditions other than neurofibromatosis type 2.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

# **Policy Coverage Criteria**

Implant	Medical Necessity	
Unilateral use of an	Unilateral use of an auditory brainstem implant (using surface	
auditory brainstem implant	electrodes on the cochlear nuclei) may be considered medically	
	necessary when ALL of the following criteria are met:	
	The individual has neurofibromatosis type 2	
	Age 12 years or older	
	• The individual became deaf because of bilateral resection of	
	neurofibromas of the auditory nerve.	
	An auditory brainstem implant is considered investigational	
	for all other conditions including non-neurofibromatosis type	
	2 indications.	

Implant	Investigational	
Bilateral use of an auditory	Bilateral use of an auditory brainstem implant is considered	
brainstem implant	investigational.	
Penetrating electrode	Penetrating (vs. surface electrodes on the cochlear nuclei)	
auditory brainstem implant	electrode auditory brainstem implant is considered	
(PABI)	investigational.	

#### **Documentation Requirements**

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Office visit notes that contain relevant history and physical supporting:
  - Diagnosis of neurofibromatosis type 2 (the tumors are commonly called vestibular schwannomas or acoustic neuromas)
  - That the member is completely deaf due to surgical removal of neurofibromas on the auditory nerve of both ears

# Coding



Code	Description
СРТ	
92640	Diagnostic analysis with programming of auditory brainstem implant, per hour
HCPCS	
S2235	Implantation of auditory brain stem implant

**Note**: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

# **Related Information**



Source: https://www.mayoclinic.org/testsprocedures/auditory-brainstem-implant/about/pac-20384649 Accessed March 24, 2023



Source: http://www.regmed.unituebingen.de/?q=en/a-difficult-nut-to-crackregeneration-in-the-central-nervous-system Resource Archived.

# **Definition of Terms**

**Neurofibromatosis type 2 (NF2):** A rare hereditary condition commonly associated with bilateral vestibular schwannomas, which are benign tumors that occur on the nerves of the inner ear and cause loss of hearing and balance. These tumors are also known as acoustic neuromas.



# **Consideration of Age**

The age listed in the policy statement is based on US Food and Drug Administration approval of the auditory brainstem implant device for ages 12 and older.

#### **Evidence Review**

### Description

An auditory brainstem implant (ABI) is designed to restore some hearing in people with neurofibromatosis type 2 (NF2) who are rendered deaf by bilateral removal of neurofibromas involving the auditory nerve. ABIs have also been studied to restore hearing for other nonneurofibromatosis indications.

#### Background

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 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, individuals with large, long-standing tumors may not benefit from the device.<sup>1</sup>

ABIs are also being studied to determine whether they can restore hearing for other nonneurofibromatosis 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.<sup>2</sup>

# **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. The relevant outcomes are functional outcomes, guality 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 US Food and Drug Administration (FDA) approval of the Nucleus 24 device in 2000 was based on a prospective case series of 90 individuals 12 years of age or older, of whom 60 had the implant for at least three 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 individuals 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 individual population 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. The 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, 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 individuals 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 also 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 outcomes.

# **Ongoing and Unpublished Clinical Trials**

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



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

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

# **Practice Guidelines and Position Statements**

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

Guidelines or position statements will be considered for inclusion 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 Health and Care Excellence

In 2005, NICE issued guidance on interventional procedures for auditory brainstem implants.<sup>22</sup> 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."

### 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.

### **Regulatory Status**

In 2000, the Nucleus 24 Auditory Brainstem Implant System (Cochlear Corp.) was approved by the 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.<sup>1</sup> 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.<sup>3</sup>

FDA product code: MCM.

#### References

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# History

Date	Comments
05/01/18	New policy, approved April 10, 2018, effective August 3, 2018. Add to Surgery section. This policy was previously archived but it is now being reinstated. Unilateral use of an auditory brainstem implant may be considered medically necessary when criteria are met, considered investigational for all other conditions. PABI and Bilateral use of an auditory brainstem implant are considered investigational. Image added. Added definition for neurofibramotosis type 2.
09/21/18	Minor update. Added Consideration of Age information.
05/01/19	Annual Review, approved April 2, 2019. Policy updated with literature review through December 2018; no references added. Policy statements unchanged.
05/01/20	Annual Review, approved April 7, 2020. Policy updated with literature review through December 2019; reference added and section summary for neurofibromas added. Policy statements unchanged
05/01/21	Annual Review, approved April 1, 2021. Policy updated with literature review through January 11, 2021; references added. Policy statements unchanged.
05/01/22	Annual Review, approved April 11, 2022. Policy updates with literature review through December 16, 2021; no references added. Policy statements unchanged.
05/01/23	Annual Review, approved April 10, 2023. Policy updates with literature review through January 3, 2023; no references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
06/15/23	Updated Related Policies. 7.01.03 is replaced by 7.01.547 Implantable Bone Conduction and Bone-Anchored Hearing Aids and 7.01.05 is replaced with 7.01.586 Cochlear Implant.
05/01/24	Annual Review, approved April 8, 2024. Policy updates with literature review through December 18, 2023; no references added. Policy statements unchanged.
05/01/25	Annual Review, approved April 7, 2025. Policy updates with literature review through December 31, 2024; references added. Policy statements unchanged.

**Disclaimer**: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review



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**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

