BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Auditory Brain Stem Implant

Policy #: 146
Latest Review Date: February 2025
Category: Surgery

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **unilateral auditory brain stem implants** that are FDA-approved as a **covered** benefit in carefully selected patients with **neurofibromatosis type 2** who are at least 12 years of age or older and who are rendered deaf due to bilateral resection of neurofibromas of the auditory nerve.

Blue Advantage will treat **bilateral** use of an auditory brainstem implant as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **upgrades of existing components for next-generation devices** as a **covered** benefit when the patient's existing components are inadequate to the point of interfering with the activities of daily living or the components are no longer functional.

Blue Advantage will treat **upgrades of an existing, functioning external system to achieve aesthetic improvement** such as smaller profile components, or a switch from a body-worn, external sound processor to a behind-the-ear (BTE) model, as a **non-covered** benefit.

Blue Advantage will treat **an auditory brainstem implant** as a **non-covered** benefit and as **investigational** for all other conditions, **including non-neurofibromatosis type 2 indications.**

Blue Advantage will treat **penetrating electrode auditory brainstem implant (PABI)** as a **non-covered** benefit and **investigational**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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.

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 the 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.

KEY POINTS:

The most recent literature update was performed through December 31, 2024.

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 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.

Practice Guidelines and Position Statements
National Institute for Health and Care Excellence
In 2005, National Institute Health and Care Excellence issued guidance on interventional procedures for auditory brainstem implants. 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."

U.S. Preventive Services Task Force Recommendations:
Not applicable.

KEY WORDS:
Auditory brain stem implant (ABI), neurofibromatosis II, neurofibromas, auditory nerve, penetrating electrode brainstem implant, PABI, Nucleus 24® Auditory Brainstem Implant System, Nucleus ABI541

APPROVED BY GOVERNING BODIES:
In 2000, the Nucleus® 24 Auditory Brainstem Implant System (Cochlear Corp.) was approved by the U.S. Food and Drug Administration (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 neurofibromatosis type 2. The Nucleus 24 Auditory Brainstem Implant System (Cochlear Corp.) labeling states: "The efficacy of bilateral implantation with the ABI has not been studied." The Nucleus 24 is currently 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 implant is indicated for individuals 12 years of age or older who have been diagnosed with neurofibromatosis type 2.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

92640	Diagnostic analysis with programming of auditory brainstem implant, per hour

HCPCS:

S2235	Implantation of auditory brain stem implant

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, August 2006
Available for comment September 1-October 16, 2006
Medical Policy Group, August 2008
Medical Policy Group, August 2010
Available for comment July 23-September 6, 2010
Medical Policy Group, September 2012
Medical Policy Group, December 2013
Medical Policy Group, November 2014
Medical Policy Group, March 2015
Medical Policy Group, September 2016
Medical Policy Group, February 2017
Available for comment March 1 through April 14, 2017
Medical Policy Group, February 2018
Medical Policy Group, February 2019
Medical Policy Group, February 2020
Medical Policy Group, February 2021
Medical Policy Group, February 2022
Medical Policy Group, February 2023
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.

Medical Policy Group, March 2024
UM Committee, March 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, February 2025

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.