



BlueCross BlueShield
of Alabama

Name of Policy:

Auditory Brain Stem Implant

Policy #: 146
Category: Surgery

Latest Review Date: December 2013
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

The auditory brain stem implant is a device designed to restore some hearing in people with neurofibromatosis type II who are rendered deaf by bilateral removal of the characteristic neurofibromas involving the auditory nerve. The device consists of a receiver/stimulator, a pocket sized speech processor worn on the body, and the microphone/headset. During surgery, the receiver/stimulator is implanted in the temporal bone behind the ear. A wire leads from the receiver/stimulator to a series of electrodes that are implanted on the surface of the cochlear nerve in the brainstem. The speech processor and microphone/headset pick up sound and change it to electrical impulses that are sent to the implanted receiver/stimulator. The impulses travel down the wire to the electrodes, which electrically stimulate multiple sites on the cochlear nucleus, which is then processed normally by the brain.

In October, 2000, one device 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).

Policy:

Auditory brain stem implants that are FDA approved **meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage in carefully selected patients with neurofibromatosis type II 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.

Upgrades of existing components for next generation devices meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage 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.

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, **do not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage.

Penetrating electrode auditory brainstem implant (PABI) does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.
(Effective on or after July 9, 2010)

Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate 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.

Key Points:

Auditory Brainstem Implants

The FDA approval of the Nucleus 24 Auditory Brainstem Implant System was based on results of a case series of 90 patients with neurofibromatosis type II, ages 12 and older. This series of adult and adolescent ABI recipients included 60 subjects studied for device effectiveness and 30 subjects who had yet to reach the 3 to 6 month evaluation interval. Of the 90 subjects, 26 patients experienced 28 complications. These included: 16 pts who were unable to perceive sound with the ABI due to migration or misplacement of the electrode; 2 pts with post op flap complications that required surgical explantation of the device; and 4 pts with minor problems such as dizziness or headache. There were no device failures or serious device malfunctions. 72 of 90 (82%) implanted subjects were able to perceive sound and use the device postoperatively.

Sixty subjects were studied 3 to 6 months post op for device effectiveness using a standard battery of recorded audiological tests, including environmental sound identification, closed- and open-set speech perception, and lip-reading enhancement. Overall, device benefit was defined as a statistically significant enhancement of lip-reading, or a significantly above-chance score on two or more of the five sound-alone tests. Based on this definition, a total of 95% (57 of 60) subjects derived benefit from the ABI device. As noted earlier, 16 of 90 pts did not receive auditory stimulation from the device postoperatively. To place the electrode array on the surface of the cochlear nucleus, the surgeon must be able to visualize the specific anatomic landmarks. Many NF-2 patients have large tumors that compress the brainstem and distort the anatomy, so it may be difficult for the surgeon to correctly place the array. For this reason, patients with large, long-standing tumors may not benefit from the ABI device.

In 2001, Otto, et al, published a summary article on implantable electronic otologic devices and presented some case studies. He noted that ABI has been used to treat deafness from NF-2 since 1979. Many factors may affect use and benefit from an ABI: general physical and mental health, medications that affect alertness, visual acuity as it affects lip-reading, age and social activity level, and presence of a support group. The outcomes of the clinical trials have shown that the device is safe and effective for use in treating deafness from NF-2. There is still progress to be made, such as improving the electrode/tissue interface.

August 2008 Update

No new information was located on a literature search that would alter the coverage statement on this policy.

August 2010 Update

Auditory Brainstem Implants

A recent search of the literature did not identify any new high-quality evidence that would alter previous conclusions.

Penetrating Electrode Auditory Brainstem Implants

Otto et al (2008) conducted a prospective clinical trial (n=10) with patients with NF2 and who received a penetrating electrode auditory brainstem implant (PABI) after vestibular schwannoma removal. The PABI is an extension of the ABI technology that uses surface electrodes on cochlear nuclei. 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 the pitch range, and high selectivity, but these properties did not result in improved speech recognition. These data are inadequate to draw conclusions regarding the effectiveness of PABI as compared to conventional ABI.

Schwartz et al (2008) discuss in a review article the future directions in central implants for hearing, including PABI, the use of ABI in non-tumor patients, and the auditory midbrain implant. The evidence for these devices is insufficient to draw conclusions regarding impact on the net health outcome. Therefore, all are considered investigational.

September 2012 Update

Auditory Brainstem Implant System

In 2012, Sanna et al reported on 25 ABIs placed in 24 patients with NF2. In this retrospective case study, patients were followed up for a range of 2–53 months. One patient died due to NF2 progression. Sound recognition was present in 19 patients of whom 11 had some word recognition and 8 had good speech recognition (50% speech discrimination in 4 patients and 75-100% speech discrimination and telephone use in 4 patients). A multivariate analysis did not identify any factors that were statistically significant in predicting ABI performance outcomes. The authors also conducted a review of the literature on ABIs and found it difficult to compare outcomes as reporting methods and outcomes measured were inconsistent and imprecise.

In a 2010 retrospective review, the authors previously cited, V. Colletti et al, reported on the complications from ABI surgery in 83 adults and 31 children, 78 of who had non-tumor cochlear or cochlear nerve disorders. The authors found complication rates were similar to cochlear implant surgery. Additionally, major and minor complications were significantly fewer in non-tumor patients than in NF2 patients. These authors concluded ABIs can be used in a wider population of patients than only those with NF2. However, this review did not evaluate hearing outcomes.

December 2013 Update

No new literature was identified to change the policy statement.

Summary

The Nucleus 24 Auditory Brainstem (ABI) Implant received FDA approval only for patients with neurofibromatosis type 2 (NF2) following tumor removal. The available evidence for unilateral use of ABI devices in patients with NF2 is sufficient to demonstrate improvements in net health outcomes. Therefore, the policy statement indicates an auditory brainstem implant may be considered medically necessary in this condition.

ABIs hold promise for patients with cochlear and cochlear nerve abnormalities when cochlear implants are not indicated. However, studies on ABIs for non-NF2 conditions are limited with

small numbers of patients and insufficient data to make scientific conclusions. Given the lack of both high-quality evidence and FDA approval, ABI for non-NF2 conditions and bilateral ABI are considered investigational. Penetrating electrode auditory brainstem implant is also considered investigational since the very limited evidence available is insufficient to draw conclusions on health outcomes.

Guidelines and Position Statements

In January 2005, National Institute for Clinical Excellence (NICE) issued Interventional Procedure Guidance 108, *Auditory Brain Stem Implants*. 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.”

Key Words:

Auditory brain stem implant (ABI), neurofibromatosis II, neurofibromas, auditory nerve, penetrating electrode brainstem implant, PABI

Approved by Governing Bodies:

Nucleus 24 Auditory Brainstem Implant System (Cochlear Corporation) is the only device with FDA approval for auditory brainstem implantation—October 20, 2000.

Benefit Application:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan.

Pre-certification/Pre-determination requirements: Not applicable

Current Coding:

CPT codes:

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

HCPCS:

S2235 Implantation of auditory brain stem implant

References:

1. Colletti L. Beneficial auditory and cognitive effects of auditory brainstem implantation in children. *Acta Otolaryngol*, September 2007; 127(9): 943-946.
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5. Ebinger K, Otto S, Arcaroli J, et al. Multichannel auditory brainstem implant: U.S. clinical trial results, *Journal of Laryngology Otology Supplement*, 2000; 27: 50-3.
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13. Otto SR, Shannon RV, Wilkinson EP, et al. Audiologic outcomes with the penetrating electrode auditory brainstem implant. *Otol Neurotol*, December 2008; 29(8): 1147-1154.
14. Sanna M, Di Lella F, Guida M et al. Auditory brainstem implants in NF2 patients: results and review of the literature. *Otol Neurotol* 2012; 33(2):154-64.
15. Schwartz MS, Otto SR, Shannon RV, et al. Auditory brainstem implants. *Neurotherapeutics*, January 2008; 5(1): 128-136.
16. Toh E, Luxford W. Cochlear and brainstem implantation, *Otolaryngologic Clinics of North America*, 2002; 35(2).

Policy History:

Medical Policy Group, November 2003 (1)

Medical Policy Administration Committee, December 2003

Available for comment December 16, 2003-January 29, 2004

Medical Policy Group, November 2005 (1)

Medical Policy Group, August 2006 (2)

Medical Policy Administration Committee, August 2006

Available for comment August 30-October 13, 2006

Medical Policy Group, August 2008 (1)

Medical Policy Group, August 2010 (1): Description, Key Points updated, Key words added, New policy non-coverage statement added

Medical Policy Administration Committee, July 2010

Available for comment July 23-September 6, 2010

Medical Policy Group, September 2012 (1): Update to Key Points, and References related to MPP update; no change to policy statement

Medical Policy Panel March 2013

Medical Policy Group, December 2013 (2): No new references identified that would change policy statement.

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.