Medical Coverage Policy | Auditory Brainstem Implant

EFFECTIVE DATE: 03|02|2010
POLICY LAST UPDATED: 04|04|2017

OVERVIEW
This policy documents the coverage determination for Auditory Brain Stem Implant. 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 non-neurofibromatosis indications.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Unilateral use of an auditory brainstem implant (using surface electrodes on the cochlear nuclei) is considered medically necessary in patients with neurofibromatosis type 2 (ICD-10 diagnosis code Q85.02), 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 considered not medically necessary for all other conditions including non-neurofibromatosis type 2 indications as the evidence is insufficient to determine the effects of the technology on health outcomes.

Bilateral use of an auditory brainstem implant is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Penetrating electrode auditory brainstem implant (PABI) is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND
The auditory brainstem implant (ABI) is a device designed 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 to an electrical signal that is transferred to a receiver/stimulator that is implanted in the temporal bone. The receiver stimulator is, in turn, attached to an electrode array that is 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. ABIs are also being studied to restore hearing for other non-neurofibromatosis indications.

One device that has received approval by the U.S. Food and Drug Administration (FDA) for auditory brainstem implantation is 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).

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 select patients with bilateral complete cochlear aplasia and demonstrated absence of a cochlear nerve on imaging and electrophysiologic testing. In patients with other non-NF2 conditions, ABIs have not demonstrated hearing benefits over cochlear implants. 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 not medically necessary. Penetrating electrode auditory brainstem implant is also considered not medically necessary because the very limited evidence available is insufficient to draw conclusions on health outcomes

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 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.

REGULATORY STATUS

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 labeling states: "The efficacy of bilateral implantation with the ABI [auditory brainstem implant] has not been studied." The Nucleus® 24 is now obsolete.

In June 2016, the Nucleus ABI541 Auditory Brainstem Implant (Cochlear Corp.) was approved by 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 neurofibromatosis type 2.

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. 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 neurofibromatosis type 2 [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 non-NF2 conditions. 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 ABI541to 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. Therefore, this service is not medically necessary for BlueCHiP for Medicare and Commercial products.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are covered if medically necessary for patients 12 years of age older with a diagnosis of Neurofibromatosis type 2:

CPT Code:

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

HCPCS Code:

S2235 Implantation of auditory brainstem implant

ICD-10 Diagnosis Code:

Q85.02 Neurofibromatosis, type 2

RELATED POLICIES

None

PUBLISHED

Provider Update, June 2017
Provider Update, Sep 2016
Provider Update, June 2015
Provider Update, Oct 2014
Provider Update, May 2013
Provider Update Apr 2012
Provider Update, May 2011
Provider Update, May 2010

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