Medical Coverage Policy | Auditory Brainstem Implant

EFFECTIVE DATE: 03|02|2010
POLICY LAST UPDATED: 07|19|2016

OVERVIEW
This policy documents the coverage determination for Auditory Brain Stem Implant. The auditory brainstem implant (ABI) is a device designed to restore some hearing in people with neurofibromatosis type 2 (NF2) who are rendered deaf by bilateral removal of the characteristic neurofibromas involving the auditory nerve.

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; ICD-9 diagnosis code 237.72), 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 there are inadequate data to permit scientific conclusions regarding its efficacy.

Bilateral use of an auditory brainstem implant is considered not medically necessary as there are inadequate data to permit scientific conclusions regarding its efficacy.

Penetrating electrode auditory brainstem implant (PABI) is considered not medically necessary as there are inadequate data to permit scientific conclusions regarding its efficacy.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage when services are 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

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

HCPCS Code:
S2235

ICD-9 Diagnosis Code:
237.72 Neurofibromatosis, type 2

ICD-10 Diagnosis Code:
Q85.02 Neurofibromatosis, type 2

RELATED POLICIES

None

PUBLISHED

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

REFERENCES:

1. Nucleus® 24 Auditory Brainstem Implant System. FDA Summary of Safety and Effectiveness. Available online at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p000015. Last accessed July, 2016.

2. Ebinger K, Otto S, Arcaroli J et al. Multichannel auditory brainstem implant: US clinical trial results. J Laryngol Otol Suppl 2000; (27):50-3.

3. Matthies C, Brill S, Kaga K et al. Auditory brainstem implantation improves speech recognition in neurofibromatosis type II patients. ORL J Otorhinolaryngol Relat Spec 2013; 75(5):282-95.

4. 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

5. Goffi-Gomez MV, Magalhaes AT, Brito Neto R et al. Auditory brainstem implant outcomes and MAP parameters: report of experiences in adults and children. Int J Pediatr Otorhinolaryngol 2012; 76(2):257-64.

6. 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 2014; 271(1):3-13.

7. 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 2014; 35(2):260-70.

8. Colletti V, Fiorino FG, Carner M et al. Auditory brainstem implant as a salvage treatment after unsuccessful cochlear implantation. Otol Neurotol 2004; 25(4):485-96; discussion 96.

9. 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 2013; 122(10):605-12.

10. Colletti V, Carner M, Miorelli V et al. Auditory brainstem implant (ABI): new frontiers in adults and children. Otolaryngol Head Neck Surg 2005; 133(1):126-38.