EFFECTIVE DATE: 03/02/2010
POLICY LAST UPDATED: 08/05/2014

OVERVIEW

This policy documents the coverage determination for Auditory Brain Stem Implant. The auditory brain stem 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.

PRIOR AUTHORIZATION

Not Applicable

POLICY STATEMENT

BlueCHiP for Medicare and Commercial

Use of a unilateral auditory brain stem implant (using surface electrodes on the cochlear nuclei) is considered **medically necessary** in patients with neurofibromatosis type 2 (diagnosis code 237.72), 12 years of age or older, who are rendered deaf due to bilateral resection of neurofibromas of the auditory nerve.

An auditory brain stem 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 brain stem 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.

MEDICAL CRITERIA

Not Applicable

BACKGROUND

The auditory brain stem 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 device 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 brain stem, 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.

One device has received approval by the U.S. Food and Drug Administration (FDA) for auditory brain stem 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).

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 medically unnecessary. Penetrating electrode auditory brainstem implant is also considered medically unnecessary because the very limited evidence available is insufficient to draw conclusions on health outcomes.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable Services Not Medically Necessary coverage.

CODING

BlueCHiP for Medicare and Commercial

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

CPT	**92640**
HCPCS	**S2235**
ICD 9	**Diagnosis Code: 237.72**
ICD10	**Diagnosis Code: Q85.02**

RELATED POLICIES

None

PUBLISHED

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 February, 2014.

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.

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS