Auditory Brain Stem Implant

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Auditory Brain Stem Implant:
The auditory brain stem implant is designed to restore some hearing in individuals with neurofibromatosis type II who are rendered deaf by bilateral removal of the characteristic neurofibromas involving the auditory nerve. External component consists of a speech processor. Internal components include a receiver/stimulator that is implanted in the temporal bone and 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.

Penetrating Electrode Auditory Brain Stem Implant (PABI):
An extension of the auditory brain stem implant technology. PABI uses 8 to 10 penetrating microelectrodes with a separate array of 10 to 13 surface electrodes and has been investigated as a method to improve speech recognition.
AUDITORY BRAIN STEM IMPLANT (cont.)

Criteria:

➢ Unilateral use of an auditory brain stem implant using surface electrodes on the cochlear nuclei is considered medically necessary for an individual 12 years of age and older with neurofibromatosis type II, who is rendered deaf due to a bilateral resection of neurofibromas of the auditory nerve.

➢ Bilateral use of an auditory brain stem implant is considered experimental or investigational based upon:

   1. Insufficient evidence to support improvement of the net health outcome, and
   2. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

➢ Penetrating electrode auditory brain stem implant (PABI) is considered experimental or investigational based upon:

   1. Insufficient evidence to support improvement of the net health outcome, and
   2. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

➢ Auditory brain stem implant for all other conditions not previously listed is considered experimental or investigational based upon:

   1. Lack of final approval from the Food and Drug Administration, and
   2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
   3. Insufficient evidence to support improvement of the net health outcome, and
   4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
   5. Insufficient evidence to support improvement outside the investigational setting.
AUDITORY BRAIN STEM IMPLANT (cont.)

Resources:


FDA 510K Summary for Nucleus® 24 Auditory Brain Stem Implant System™:

- FDA-approved indication: Persons 12 years of age and older with Neurofibromatosis Type II. Implantation may occur during first or second side tumor removal or in persons with previously removed acoustic tumors bilaterally.