

# **Clinical Commissioning Policy: Auditory brainstem implant with congenital abnormalities of the auditory nerves of cochleae**

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**Document Status**

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# **Clinical Commissioning Policy: Auditory brainstem implant with congenital abnormalities of the auditory nerves or cochleae**

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**Prepared by NHS England Specialised Services Clinical Reference Group for Specialised Ear Surgery**

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## **Policy Statement**

NHS England will commission auditory brainstem implant with congenital abnormalities of the auditory nerves of cochleae in accordance with the criteria outlined in this document. In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources. This policy document outlines the arrangements for funding of this treatment for the population in England.

## **Equality Statement**

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

## **Plain Language Summary**

### **About auditory brainstem implants**

Auditory brainstem implants (ABIs) can help a very small number of patients whose auditory (hearing) nerve is not working. The brainstem is at the bottom of the brain, where it joins the spinal cord.

Most patients are small children whose inner ear (cochlea) or nerve did not develop properly.

## OFFICIAL

A device is inserted by an operation on the brain ('neurosurgery'). It is put directly against the brainstem. Useful hearing develops in some patients – but it is not fully normal. This happens particularly in children who:

- have the treatment at a young age
- do not have other developmental disabilities.

Most children will not go on to have normal language. They will have to also use other ways of communicating - such as sign language.

The type of surgery needs an expert team for the operation to insert the device. It also needs an expert team for getting the best out of the implant and training for the patient.

### **What we have decided**

NHS England has carefully reviewed the evidence for using auditory brainstem implants and concluded that there is sufficient evidence to consider supporting routine commissioning.

## 1 Introduction

Auditory Brainstem Implantation (ABI) is a process that involves the surgical implantation of an electrode array adjacent to the brainstem to provide direct electrical stimulation of the cochlear nucleus and subsequent central auditory pathways. A microphone and sound processor unit worn on the side of the head transmits to the internal receiver-stimulator package. The resulting electrical stimulation of the cochlear nucleus may provide auditory sensation but does not restore normal hearing.

ABI is already routinely commissioned for patients with neurofibromatosis type 2 (NF2) within the specification for that service; but not for other conditions. This policy sets out commissioning policy for patients with conditions other than NF2 who have no functional hearing because of congenital abnormalities of the auditory nerves or the cochlea, rendering them unable to gain adequate benefit from conventional well-fitted hearing aids or cochlear implants.

This intervention is an auditory brain stem implant. The primary clinical indication is profound deafness in children aged five years or under, who have no functional hearing as a result of congenital abnormalities affecting the auditory nerve or the cochlea, thus rendering them unable to gain adequate benefit from conventional well-fitted hearing aids or cochlear implants.

## 2 Definitions

Auditory brainstem implantation is a process which includes patient assessment of patient suitability, implantation of the device, tuning of the device, training the patient and family and lifetime follow up.

## 3 Aims and Objectives

This policy aims to ensure equitable access throughout England to patients who might benefit from ABI.

The objectives are to ensure that patients are assessed in expert centres that the right patients are selected for treatment and that patients in whom an ABI is inserted receive the necessary device tuning and patient training for optimal benefit from the device.

## **4 Epidemiology and Needs Assessment**

It is estimated that about 15 children per annum would be assessed for auditory brainstem implantation per annum and that about 9 would go on to have the surgery.

## **5 Evidence base**

The published evidence all consists of case series with no randomized controlled trials. In the case of cochlear aplasia, however, it is clear that without treatment the patient will remain without functional hearing.

A systematic review (Merkus 2014) review emphasizes the importance of correct patient selection.

The large series from Colletti (2014) shows that good results can be obtained in many (but not all) patients when selected and treated at an expert centre. On a standard measure of hearing, 30 out of 64 consecutive children treated with an ABI achieved a score of 4 or better on a 5 point scale of hearing, of whom 20 were able to understand free speech (score 5/5). Higher scores were achieved in children treated young, and in those with no other developmental disabilities.

In expert hands, the complication rates are similar to cochlear implantation with a major complication rate of approximately 1% (Colletti 2010). However the severity of complications is greater as these include intracranial complications such as stroke, bleeding and meningitis with the potential for permanent neurological dysfunction. No papers were identified evaluating cost effectiveness.

A European consensus group has published two statements on the use of ABI in non NF2 patients (Sennaroglu 2011, Sennaroglu in press).

## **6 Criteria for Commissioning**

The primary indication is a patient aged five years or under who has bilateral hearing loss, with no functional hearing secondary to congenital abnormalities of the auditory nerve or the cochlea, rendering them unable to gain adequate benefit from conventional well-fitted hearing aids or cochlear implants.

Colletti (2014) and Sennaroglu (2011) indicate that the criteria that should be taken into account when selecting children for the procedure are:

- Presence of other developmental disorders (ABIs are more likely to be successful in children who do not have other developmental disorders, although visual impairment should not be a contraindication)
- Family support structures (ABIs are more likely to be successful in children who have a supportive family structure, including a commitment to learn sign language)
- The age of the child (ABIs are more likely to be successful in young children, aged five years and under).

The health of the child (given the complexity of the surgery required, the implantation of ABIs should only be considered in children in good physical health).

## **7 Patient Pathway**

Patients should be referred for assessment to the ABI providers, usually from local specialist audiology, ENT services or Audiological Medicine.

## **8 Governance Arrangements**

ABI insertion for non-tumour patients will only be provided in providers with ample experience of ABI. In practice this is likely to mean the current providers of ABI for NF2 patients in England.

## **9 Mechanism for Funding**

The treatment is not under national tariff. A local tariff will be developed for the funding of the agreed care pathway.

## **10 Audit Requirements**

Although ABI is no longer experimental, worldwide experience remains limited, and lifetime follow up has not been achieved due to newness of the technology. A clinical registry must be kept of all patients receiving an ABI under this policy, to include for each patient clinical outcomes and adverse events.

## **11 Documents which have informed this Policy**

All relevant statutory guidance will apply to this policy.

See also:

National Institute for Health and Clinical Excellence. Interventional Procedure Guidance 108. Auditory brain stem implants.

## **12 Date of Review**

This document will be reviewed when information is received which indicates that the policy requires revision.

## References

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