NHS England

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

Reference: NHS England D09X04

DRAFT FOR PUBLIC CONSULTATION

Information Reader Box (IRB) to be inserted on inside front cover for documents of 6 pages and over, with Publications Gateway reference number assigned after it has been cleared by the Publications Gateway Team. Publications Gateway guidance and the IRB can be found on the Intranet.

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

First published: Month Year

Prepared by NHS England Highly Specialised Commissioning Team

Published by NHS England, in electronic format only.

Contents

Equality Statement

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

Plain Language Summary

Auditory brain stem implants are a technology which can help a very small number of patients whose auditory (hearing) nerve is not working. Most patients are small children whose inner ear (cochlea) or nerve did not develop properly. A device is inserted by neurosurgery directly against the brainstem. Useful, though not fully normal, hearing develops in some patients, particularly those who receive treatment at a young age and who do not have other developmental disabilities. Most children will not acquire normal language but will have to supplement with other communication methods such as sign language. The technique requires an expert team not only for the operation to insert the device but also for subsequent fine tuning of the device and training for the patient.

1. Introduction

Auditory Brainstem Implantation 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.

2. The proposed intervention and clinical indication

The proposed intervention Is an auditory brain stem implant. The primary indication is a patient aged five years or under who has 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.

3. Definitions

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

4. Aim 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.

5. 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 nine would go on to have the surgery.

6. 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).

7. Proposed criteria for commissioning

The primary indication is a patient aged five years or under who has 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)
- 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).

8. Proposed patient pathway

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

9. Proposed 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.

10. Proposed mechanism for funding

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.

11. Proposed 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.

12. 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 Guideline 108. Auditory brain stem implants. Available from: http://www.nice.org.uk/nicemedia/live/11086/30959/30959.pdf

13. Date of review

This policy will be reviewed in March 2017 unless information is received which indicates that the proposed review date should be brought forward or delayed.