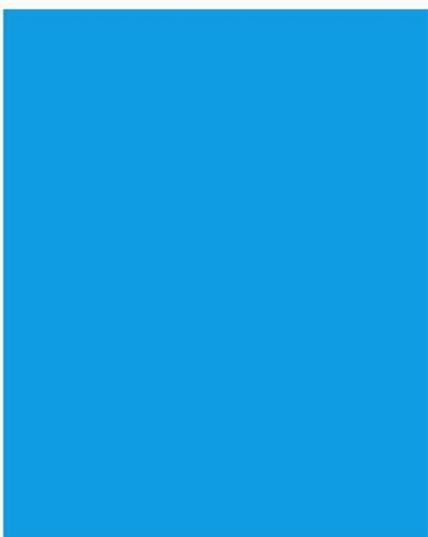


**Clinical Commissioning  
Policy: Bone Anchored  
Hearing Aids**

**April 2013**

**Reference: NHSCB/ D09/P/a**



# **NHS Commissioning Board**

## **Clinical Commissioning Policy: Bone Anchored Hearing Aids**

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**Prepared by the NHS Commissioning Board Clinical Reference Group for  
Specialised Ear Surgery**

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## Contents

Policy Statement .....	4
Equality Statement .....	4
Plain Language Summary .....	4
1. Introduction .....	5
2. Definitions .....	5
3. Aim and objectives .....	5
4. Criteria for commissioning .....	6
5. Patient pathway .....	8
6. Governance arrangements .....	8
7. Epidemiology and needs assessment .....	8
8. Evidence base .....	8
9. Rationale behind the policy statement .....	9
10. Mechanism for funding .....	9
11. Audit requirements .....	9
12. Documents which have informed this policy .....	10
13. Links to other policies .....	10
14. Date of review .....	10
15. Glossary .....	10
References .....	11

## **Policy Statement**

The NHS Commissioning Board (NHS CB) will commission Bone Anchored Hearing Aids (BAHAs) for hearing loss in accordance with the criteria outlined in this document.

In creating this policy the NHS CB 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**

The NHS CB 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. The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB 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 they are responsible, including policy development, review and implementation.

## **Plain Language Summary**

The Bone-anchored hearing aid system (BAHA) is a hearing aid which uses the principle of bone conduction. In normal hearing sound may be transmitted to the inner ear both by air (through the external ear canal) or through the bones of the skull. In individuals who are unable to hear using air conduction, either due to a congenital malformation of the ear canal or due to chronic ear infection, a hearing aid which utilises bone conduction is the most appropriate.

There is evidence to support the use of bone anchored hearing devices in adults and children with hearing impairment that is not adequately corrected by conventional air conduction hearing aids. The intervention is safe and of proven benefit.

The care of children with congenital microtia **MUST** be coordinated by a multidisciplinary team that can provide appropriate hearing and reconstructive support.

Information on the outcome of treatments for these patients will be collected and considered when this policy is reviewed.

## 1. Introduction

There is evidence to support the use of bone anchored hearing devices in adults and children with hearing impairment that is not adequately corrected by conventional air conduction hearing aids. The intervention is safe and of proven benefit.

The care of children with microtia **MUST** be coordinated by a multidisciplinary team that can provide appropriate hearing and reconstructive support.

## 2. Definitions

The Bone-anchored hearing aid system (BAHA) is a hearing aid which uses the principle of bone conduction. In normal hearing sound may be transmitted to the inner ear both by air (through the external ear canal) or through the bones of the skull. In individuals who are unable to hear using air conduction, either due to a congenital malformation of the ear canal or due to chronic ear infection, a hearing aid which utilises bone conduction is the most appropriate.

The BAHA comprises a vibration transducer which is coupled to a titanium implant anchored to the temporal bone of the skull. Surgery is required for the placement of the titanium fixture. The BAHA system offers advantages over conventional bone conduction hearing aids. Conventional bone conduction aids require a transducer, placed on the opposite side of the head, to be held in place by a tight steel band and may cause problems with pressure effects (especially in children), an unnatural listening circumstance and loss of sound quality.<sup>1,2</sup>

## 3. Aim and objectives

The policy should ensure that patients who can be helped by a bone anchored hearing device are identified and carefully assessed. All patients for whom a conventional air conduction device is appropriate should be identified and not offered an implantable device.

It is the assessment of a patient to demonstrate that a hearing implant is the most effective clinical option that is of central importance. Alternative hearing implants for this patient group may also be considered when the patient is undergoing assessment.

#### 4. Criteria for commissioning

##### Criteria for unilateral implantation

BAHA will be funded when assessment by a multidisciplinary team leads to a clear recommendation of a BAHA<sup>1,2</sup> AND confirms all of the criteria below.

The patient has one of the following:

Permanent bilateral conductive or mixed hearing loss.

Bilateral conductive or mixed hearing loss where one ear works better than the other, but clinicians would have considered two air conducting hearing aids (ACHAs) if the type of hearing loss had not precluded their use.

Unilateral conductive hearing loss with ear canal stenosis that is unlikely to benefit from meatoplasty; or who have had revision surgery and failed to tolerate ACHA.<sup>3,4</sup>

Profound unilateral sensorineural hearing loss

AND

The patient is clinically unsuitable for other medical or surgical treatments.

Otological indications supporting the use of BAHA include:

- Congenital malformation of the middle/external or microtia.
- Chronically draining ear that does not allow the use of an air conducting hearing aid.
- Patients with bilateral conductive hearing loss due to ossicular disease (and not appropriate for surgical correction) or unable to be aided by conventional air conducting devices.

AND

The following audiological criteria should be met:

Conduction or mixed hearing loss with a bone conduction pure tone average (0.5, 1, 2, 3 kHz) threshold up to 45 dBHL for the Devino or BP 100,55dB for the Intenso and 70 dB for Cordelle II (Body Processor). In the advent of new processors being released manufacturers audiological recommendations should be followed.

Air conduction pure tone average not better than 40 dB (for Adults).

A maximum speech discrimination score better than 60% when using a phonetically balanced word list.<sup>2</sup>

AND

The patient has had preoperative counselling, and has realistic expectations about the benefits and limitations of BAHA. They must be prepared to maintain their device in the long term.<sup>2</sup>

The patient will be able to keep the area around the fixture clean, either on their own or with help from other people.<sup>5</sup>

There are no contraindications for BAHA.

### **The following should be considered as contraindications to BAHA**

#### **Absolute**

Having a bone disease that leaves the skull too thin to support a BAHA implant e.g. brittle bone disease (osteogenesis imperfecta)

Being younger than three years old.

#### **Potential**

Contraindications that may stop patients adequately maintaining their BAHA:

- Psychiatric disease
- Immature personality
- Alcohol or drug abuse

The NHS CB will not normally commission bilateral Bone Anchored Hearing Aid (BAHA) implantation. Such requests for funding will only be considered through an exceptions route.

#### **Additional considerations for BAHA implantation in children:**

In children with binaural congenital hearing loss, intervention should take place as early in life as possible; BAHA may be provided on a headband until the child is old enough for surgery. The minimum age for first surgery, as identified by the equipment manufacturer, is three years. It is recommended that implant surgery be performed in two stages in children of up to 10 years of age.

In children with bilateral conductive hearing loss; clinicians may consider bilateral BAHA if a decision is made that this would provide children with the best hearing environment in the classroom situation, following multidisciplinary clinical assessment by the BAHA team.

In children with unilateral hearing loss; BAHA would not normally be funded. Decisions should be taken on a case-by-case basis through the exceptional case process, centred on information regarding the child's development, audiometry results and communication needs.

## 5. Patient pathway

The patient pathway is described in detail in the Bone Anchored Hearing Aid specification.

## 6. Governance arrangements

Recommendations on standards for BAHA services come from a consensus statement of experts<sup>1</sup>, which states that BAHA fitting should take place in a specialist centre performing at least 15 procedures per year. The team should include an otorhinolaryngologist surgeon, audiologist and, for children, paediatric anaesthetist and speech and language therapist.

## 7. Epidemiology and needs assessment

BAHAs are only appropriate for a very small sub-set of patients. The incidence of bilateral congenital ears is 'probably 1:10,000'.<sup>1</sup> The incidence of bilateral chronic suppurative otitis media is not known, though 'clinical observation would suggest this is a considerable problem'.<sup>1</sup> Gillett *et al* note that for a catchment area of circa 300,000, they 'implanted approximately eight to 10 patients per year'.<sup>7</sup>

These figures suggest that between 1413 and 1766 BAHAs could be implanted per year in England (Census population 2011 = 53million (ONS)).

## 8. Evidence base

The reviews of BAHA all demonstrate evidence of clinical effectiveness. However this evidence is of a low quality; all the evidence comes from level 4 case series with relatively small sample sizes.<sup>2</sup>

BAHA is a safe intervention. In a study of 149 consecutive patients who underwent BAHA implantation, primarily for unilateral sensorineural hearing loss, the authors found no intra or perioperative complications. Post-operative complications occurred in 19/149 (12.8%) of the patients; these included skin overgrowth over the abutment, implant extrusion and local wound infections.<sup>13</sup>

There is currently insufficient evidence to justify commissioning bilateral implantation of BAHA. A Birmingham University review in 2005 found 5 small cases series; sample sizes ranging from 3 to 25. Methodological weaknesses encouraged positive results and the reviewers concluded that the use of bilateral BAHA was neither supported nor refuted.<sup>14</sup>

There is reasonable evidence to justify commissioning BAHA for unilateral hearing loss in specific circumstances.<sup>3, 4, 6</sup>

## 9. Rationale behind the policy statement

The BAHA consists of a permanent implant surgically inserted into the mastoid bone.

A vibrating part (permanent abutment) is then fitted onto this, and a small detachable sound processor clips onto the abutment.<sup>5</sup> The vibrating part then conducts sound through to the inner ear.

BAHAs are only appropriate for a very small sub-set of patients. It is appropriate to consider other treatment options before BAHA. The Canadian systematic review found no additional benefit in using BAHA for people previously using air conducting hearing aids (ACHA).<sup>2</sup> ACHA remains the first line treatment, and stapedectomy normally remains the second line treatment for otosclerosis<sup>8</sup> except in some older patients where BAHA is likely to be more effective than stapedectomy.<sup>9</sup>

The adult service requires a multi-disciplinary team dealing with otology and audiology within a specialised ENT service. The children's service should be located in a major paediatric centre because of the specialist anaesthetic needs.<sup>6</sup>

Cost effectiveness analysis of BAHA demonstrates an ICER of £17,610 per QALY gained. This falls within the NICE ICER threshold of £20,000- £30,000 per QALY.<sup>11</sup>

The selection criteria are based on the quality standards and good practice guidelines for BAHA for children and young people and current best available published evidence.

## 10. Mechanism for funding

From April 2013 the NHS CB will be responsible for commissioning in line with this policy on behalf of the population of England.

## 11. Audit requirements

There is currently no national database. The service specification records relevant outcome measures to be recorded. Service providers will be expected to collect and provide audit data on request

## 12. Documents which have informed this policy

The National Deaf Children's Society. Quality Standards in Bone Anchored Hearing Aids for Children and Young People. 2010

## 13. Links to other policies

This policy follows the principles set out in the ethical framework that governing the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

## 14. Date of review

April 2014

## 15. Glossary

<b>Term</b>	<b>Meaning</b>
Atresia	Absence or closure of a tubular organ/ structure.
Audiology	Pertaining to the sense of hearing.
Binaural	Relating to or involving the use of both ears.
Bilateral	Relating to both sides of the body.
Congenital	Existing from birth or before.
Conductive Hearing Loss	Due to a defect in the conduction of sound from the external ear to the inner ear. This may be due to perforations of the eardrum, fluid or infection in the middle ear, or disorders of the small bones in the middle ear (ossicles).
Microtia	Congenital abnormally small ears.
Ossicular disease	Disease affecting the "ossicles", the small bones which conduct sound through the middle ear.

Sensorineural hearing loss	May be due to a lesion of the cochlea in the inner ear, the auditory nerve or the auditory centres in the brain.
Suppurative Otitis media	Infection of the middle ear which may lead to hearing loss, suppurative means with pus present.
Transducer	A device such as a microphone or electric motor that converts one form of energy into another.
Unilateral	Relating to one side of the body.

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a trial of a CROS (Contralateral Routing of Sound) aid when assessing their suitability for the device. In general if they benefit from its use then they definitely benefit from using the BAHA” and “The total number of patients is small, perhaps only 2-3 per year across all our PCTs”

