The Department of Health considers the provision of Bilateral Bone Anchored Hearing Aids (BAHA) as a High Priority in Children with congenital bilateral atresia of the external auditory canal. Children with bilateral chronic suppurative otitis media will be given higher priority than adults with the same condition.

The Department of Health considers the provision of Unilateral Bone Anchored Hearing Aids (BAHA) for adults as a High Priority subject to the criteria within the policy.

Bilateral BAHA provision for adults will not be provided.

Clinical Background Information

The Bone-anchored hearing aid system (BAHA) is a hearing aid that uses the principle of bone conduction. BAHAs are commissioned, but only when a patient meets certain pre-defined criteria and on a unilateral basis. There are a group of patients with a severe hearing loss who cannot wear conventional hearing aids. This is either because of congenital abnormalities of the external ear canal or the fact that they have chronic infection due to middle ear disease, which has not been controlled surgically. The wearing of an insertion hearing aid in this situation tends to exacerbate infection. The procedure for establishing a bone-anchored hearing aid (BAHA) involves a small implant being inserted just behind the ear to enable the hearing aid to be attached. This will enable sound energy to pass directly through the bone to the hearing nerve.

Definition

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.
Requirements for BAHA surgery

The National Deaf Children’s Society has produced quality standards and good practice guidelines for bone-anchored hearing aids for children and young people. This document includes standards for both local and specialist services as well as for the pathway of care for the child or young person. These quality standards provide a framework for audit of BAHA services. Additional recommendations on standards for BAHA services come from a consensus statement of experts, which states that BAHA fitting should take place in a specialist centre performing at least 15 procedures per year. The BAHA team should include an ENT surgeon, audiologist and, for children, paediatric anaesthetist and speech and language therapist.

Criteria/Pathway unilateral implantation

Patients with bilateral conductive or mixed hearing loss (with an air-bone gap of greater than 30dB hearing loss), due to one of the following otological indications:

- congenital malformation of the middle /external ear or microtia;
- chronically draining ear that does not allow use of an air conduction hearing aid;
- bilateral conductive hearing loss due to ossicular disease (and not appropriate for surgical correction)

And

For whom a conventional hearing aid is not appropriate or is likely to cause harm

And

Can still benefit from sound amplification

And

Meet the following criteria:

- average bone conduction thresholds (0.5-4kHz) of <40dBHL (ear level aid), <60dBHL (body worn aid)
- speech discrimination score greater than 60%
- realistic expectations about the BAHA
- reasonable social support
- understand practical implications for maintaining the BAHA
- mechanisms in place to ensure the abutment is kept clean

Exceptional or Individual funding requests

- Patients who are not eligible for treatment under the policy may be considered for exceptionality on an individual basis. The Individual Funding and Exceptions Panel will review individual cases upon receipt of an application from the patient’s GP, Consultant or Clinician.
- The fact that a treatment is likely to be effective for a patient is not in itself a basis for exceptionality.

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 unilateral hearing loss, BAHA would not normally be provided. Decisions should be taken on a case-by-case basis through the individual funding and exceptional case panel, centred on information regarding the child’s development, audiometry results and communication needs.

Evidence (NICE/ SIGN)

In patients with conductive hearing loss due to congenital abnormality that cannot be repaired surgically or to chronic ear infections exacerbated by the use of conventional hearing aids, use of BAHA provides benefits both in terms of audiological tests and quality of life. A consensus statement of specialists reports that there is evidence that BAHA is indicated in these patients if the air-bone gap exceeds 30dB.

Patients with unilateral hearing loss are at a disadvantage in sound localisation and speech recognition in a noisy background. There is some evidence that BAHAs improve speech perception in noise and improved patient reported outcomes for unilateral sensorineural hearing loss, but no evidence of improved sound localisation. A health technology appraisal states that BAHA should be considered experimental in this group. A consensus statement of experts reports benefit of BAHA for this indication, but also states that further studies are needed. Studies of BAHA for unilateral conductive hearing loss have shown mixed audiological benefit but a small study showed benefits in patient-reported outcomes, including improvements in the area of learning for children. A consensus statement of experts found evidence of audiological and patient-reported outcomes, but added that further studies are needed. In children, however, the consensus statement recommended that, to be sure that those children with unilateral hearing loss have a normal development, they should be fitted with a hearing aid as early as possible; with BAHA being an important option in severe unilateral conductive hearing loss. They added that individual assessment and counselling of such children remains of importance.

A paper reporting recent developments in BAHA for children concludes that there is no convincing evidence in the current clinical literature, for early intervention in children with unilateral congenital conductive deafness. This paper also cited a Paediatric Workgroup on Hearing Aid amplification, which in 2000, concluded that amplification should be considered on a case-by-case basis, and centred on the child’s development, audiometry results and communication needs. The side effects to this procedure include skin reactions and loss of fixture. Revision surgery may be required. Skin infections are also more common in children. No cost-effectiveness studies of BAHA were found. A UK pilot study comparing the difference in clinic visits and treatments dispensed pre- and post- BAHA insertion in patients with chronic suppurative otitis media showed a reduction in the number of courses of drugs dispensed but did not demonstrate a statistically significant reduction in the number of visits to ENT.
Numbers of people affected and costs of procedure

The incidence of congenital atresia of the external auditory canal with associated middle ear abnormalities is estimated at 1 in 10,000 live births, with 15 – 30% of these being bilateral.

Prevalence of chronic suppurative otitis media (CSOM) which is severely exacerbated by air conduction hearing aids has been estimated as 2 – 4% of the adult population with a suggested 1 – 2 cases per 50,000 adults meeting the criteria for a BAHA (West Essex NHS).

A minority of people with otosclerosis (affects 2% of adult population) might need to resort to BAHA, representing roughly 0.1 of adults.

The average cost to insert BAHAs, including obligatory ENT and audiology follow up, is estimated to be £5,654 for adults and £8,453 for children (Plymouth NHS 2010 data), whilst other info suggests an annual recurrent cost of £3,000 (West Essex NHS). Based on UK figures, the Department of Health in the Isle of Man was likely to require provision for between four and six cases per year.

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References

Available from PH Directorate