

WellCare Health Plans, Inc.

The WellCare Group of Companies

WellCare Prescription Insurance, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

WellCare of Texas, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

HealthEase of Florida, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.

Clinical Coverage Guideline



Bone-Anchored Hearing Aid (Baha®)

Guideline Number: HS-045

Original Effective Date: 9/18/2008

Revision Date: 9/18/2009

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

Clinical Coverage Guideline HS-045

Bone-Anchored Hearing Aid (Baha®)

Original Effective Date: 9/18/2008

Revised Date(s): 9/18/2009

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

Unilateral implantation of bone-anchored hearing aids (Baha®) is considered medically necessary when the following criteria are met:

1. Unilateral or bilateral mixed or conductive hearing loss or unilateral sensorineural hearing loss; **AND**
2. Pure tone average bone conduction threshold of up to 70 dBHL (decibel hearing loss); **AND**,
3. Speech discrimination score better than 60%; **AND**,
4. At least 5 years of age*; **AND**,
5. At least one of the following conditions:
 - Documentation of chronic ear infection/inflammation
 - Congenital or surgically induced ear malformations of the external or middle ear canal
 - Tumors of the external canal and/or tympanic activity

*Surgical implantation of the Baha® device is not FDA approved for children younger than 5 years of age. The Baha® SoftBand may be used in children younger than five.

BACKGROUND:

Baha® devices are FDA-approved, bone-anchored, bone conduction hearing aids and, according to the FDA and manufacturer, are specifically indicated for patients over five years of age (FDA 510(k) K984162, 1999; BAHA, Entific Medical Systems, 2002–2004). *The devices are FDA approved for unilateral or bilateral mixed or conductive hearing loss, and for unilateral sensorineural hearing loss.* In the Baha®, the hearing aid transducer is coupled to a titanium screw located in the upper mastoid region on the temporal bone. The titanium screw protrudes through the skin. The difference between the standard bone conduction hearing aid and the bone-anchored hearing aid is direct stimulation of the bone occurs as opposed to stimulation through the skin. Thus the Baha® device transmits sound to the cochlea bypassing any conductive component that may be obstructing the sound source.

BAHA Models

There are several BAHA models available: the Baha Divino™, BAHA® Classic 300, BAHA® Compact, and the BAHA® Cordelle (Entific Medical Systems, Goteberg, Sweden). The BAHA Divino utilizes digital sound processing and a built-in directional microphone. This device may be utilized by patients with bone conduction thresholds of 45 dB. Patients with unilateral, profound sensorineural hearing loss of the indicated ear with normal contralateral hearing (defined as 20 dB HL air conduction pure tone average) may also benefit from this device. The Classic and Compact models are suitable for people with conductive or mixed hearing loss and a maximum bone conduction threshold of 45 dB. The Cordelle model is indicated for more severe hearing loss, with an average bone threshold of approximately 70 dB. The patients recommended for this device must either be unable to use conventional air conduction hearing aids or have undergone ossicular replacement surgery because of chronic otitis media, congenital malformation of the middle/external ear, or other acquired malfunctions of the middle or external ear canals which preclude the wearing of a conventional air conduction hearing aid. Patients must be able to maintain the abutment/skin interface of the BAHA.

Scientific Review

Several reviews have reported improved patient outcomes and functioning with the use of BAHA devices. Snik et al. (1995) compared the BAHA device with conventional bone conduction devices and reported improved speech recognition scores with the BAHA device. Wazen et al. (1998) reported improved speech reception threshold and patient satisfaction with use of the BAHA device. A technology literature review was conducted by the Medical Advisory Secretariat (MAS), Ontario Ministry of Health and Long Term Care (2002). The review indicated that BAHA devices have been safely implanted in adults and children with success rates of 90% and higher in most studies. In addition, they stated that BAHA devices significantly improved the free field and sound field thresholds and speech discrimination for former users of bone conduction hearing aids. Hayes conducted a technology assessment to evaluate the safety and efficacy of the BAHA device for moderate to severe conductive or mixed hearing loss (Hayes, 2005a). Hayes' (2005) concluded the evidence from several prospective studies and some retrospective reviews suggests that BAHA devices can provide significant improvements in functional gain, speech perception, and hearing ability in various listening situations, compared to air conduction hearing aids for some patients with moderate to severe conductive hearing loss. BAHA use was also associated with improvements in language development in young children.

CODING

Covered CPT® Codes

- 69710 Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
- 69711 Removal or repair of electromagnetic bone conduction hearing device in temporal bone
- 69714 Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
- 69715 Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
- 69717 Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
- 69718 Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy

Covered ICD-9-CM Procedure Codes

- 20.95** Implantation of Electromagnetic Hearing Device; Bone Conduction Hearing Device

HCPCS Codes

- L8690 Auditory Osseointegrated device, includes all internal and external components
- L8691 Auditory osseointegrated device, external sound processor, replacement

Covered ICD-9-CM Diagnosis Codes

- 389.05 Unilateral Conductive Hearing Loss
- 389.06 Bilateral Conductive Hearing Loss
- 389.15 Unilateral Sensorineural hearing loss
- 389.21 Unilateral Mixed Conductive and Sensorineural Hearing Loss
- 389.22 Bilateral Mixed Conductive and Sensorineural Hearing Loss

*Current Procedural Terminology (CPT) 2009 American Medical Association: Chicago, IL.®©

REFERENCES

1. Baha® Information, Cochlear™ website, 2008.
2. Hayes Directory, Bone-Anchored Hearing Aids, June 3, 2005.