



Children's Medical Services Health Plan (CMS Health Plan)

Missouri Care

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

Staywell of Florida

WellCare (Alabama, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Hawaii, Illinois, Indiana, Kentucky, Louisiana, Maine, Michigan, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Ohio, South Carolina, Tennessee, Texas, Washington)

WellCare Heritage Health

WellCare Prescription Insurance

WellCare TexanPlus (Medicare – Dallas & Houston markets)

Bone-Anchored Hearing Aid (Baha®)

Policy Number: HS-045

Original Effective Date: 9/18/2008

**Revised Date(s): 9/18/2009; 9/24/2010;
9/1/2011; 9/6/2012; 8/1/2013; 8/7/2014;
7/9/2015; 9/27/2016; 7/6/2017; 6/7/2018;
RETIRED 3/7/2019; REINSTATED
3/26/2019; 4/16/2020**

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.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of an enrollee's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, an enrollee's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the enrollee. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

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,

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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.

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. The BAHA Cordelle was determined to be “a viable, safe, low-morbidity hearing rehabilitation option in patients with mixed hearing loss with poor sensorineural reserve”¹.

Scientific Review. Several reviews have reported improved patient outcomes and functioning with the use of BAHA devices. A comparison of the BAHA device with conventional bone conduction devices and reported improved speech recognition scores with the BAHA device. Further studies 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. 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. Research concludes that 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.² An update to Hayes¹ demonstrating efficacy of the use among children and adults, including different BAHA models now available and long-term data. The BAHA’s efficacy was explored over a 15 year period from 1992 to 2007 of 182 pediatric patients from Birmingham Children’s Hospital in England. Data show “the BAHA is a reliable and effective treatment for selected patients. Our program currently has 97% of its children wearing their BAHA on a daily basis with continuing audiologic benefit.”³ Quality of life among individuals from the same program were measured using the Glasgow Children’s Benefit Inventory as a source of measurement – findings found “the use of a BAHA significantly enhanced general well-being, improved patient state of health (quality of life), and finally, was considered a success by patients and their families.”⁴

POSITION STATEMENT

Applicable To:

- Medicaid – All Markets (excluding KY)
- Children’s Medical Services Health Plan (CHIP)
- Medicare – All Markets

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,**

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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 cavity

*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.

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 HCPCS Level II (DME)® Codes

- L8690** Auditory Osseointegrated device, includes all internal and external components
- L8691** Auditory osseointegrated device, external sound processor, replacement
- L8692** Auditory Osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
- L8693** Auditory Osseointegrated device abutment, any length, replacement only

Covered ICD-10-PCS Codes

Refer to the following ICD-10-PCS table(s) for specific PCS code assignment based on physician documentation.

NOTE: Per ICD-10-PCS Coding Guidelines, "ICD-10-PCS codes are composed of seven characters. Each character is an axis of classification that specifies information about the procedure performed. Within a defined code range, a character specifies the same type of information in that axis of classification. One of 34 possible values can be assigned to each axis of classification in the seven-character code".

09HD04Z - 09HD46Z Medical/Surgical, Ear, Nose, Sinus, Insertion

Covered ICD-10-CM Diagnosis Codes

- C30.1** Malignant neoplasm of middle ear
- C47.0** Malignant neoplasm of peripheral nerves of head, face and neck
- C49.0** Malignant neoplasm of connective and soft tissue of head, face and neck
- C44.201, C44.202, C44.209** Unspecified malignant neoplasm of skin of ear and external auricular canal
- C44.211, C44.212, C44.219** Basal cell carcinoma of skin of unspecified ear and external auricular canal
- C44.221, C44.222** Squamous cell carcinoma of skin of ear and external auricular canal
- C44.291, C44.292, C44.299** Other specified malignant neoplasm of unspecified (C44.291) skin of ear and external auricular canal
- D14.0** Benign neoplasm of middle ear, nasal cavity and accessory sinuses
- D21.0** Benign neoplasm of connective and other soft tissue of head, face and neck
- D22.20 - D04.22** Melanocytic nevi of unspecified ear and external auricular canal

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D04.20, D04.21, D04.22	Carcinoma in situ of skin of unspecified ear and external auricular canal
H61.111, H61.112, H61.113, H61.119	Acquired deformity of pinna
H65.20 - H65.23	Chronic serous otitis media, unspecified ear (H65.20)
H65.30 - H65.33	Chronic mucoid otitis media, unspecified ear (H65.30)
H65.411 - H65.419, H65.492 - H65.499	Chronic allergic otitis media and other chronic non-suppurative otitis media
H66.20 - H66.23	Chronic atticofurcal suppurative otitis media, unspecified ear (H66.20)
H66.3X1 - H66.3X9	Other chronic suppurative otitis media
H66.90 - H66.93	Otitis media unspecified, unspecified ear (H66.90)
H80.93	Unspecified otosclerosis, bilateral
H90.0 -H90.2	Conductive hearing loss, bilateral (H90.0)
H90.11 - H90.12	Conductive hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.2	Conductive hearing loss, unspecified
H90.3	Sensorineural hearing loss, bilateral
H90.41 - H90.42	Sensorineural hearing loss, unilateral with unrestricted hearing on the contralateral side
H90.5	Unspecified sensorineural hearing loss
H90.6	Mixed conductive and sensorineural hearing loss, bilateral
H90.71 - H90.72	Mixed conductive and sensorineural hearing loss, unilateral with unrestricted hearing on the contralateral side
H90.8	Mixed conductive and sensorineural hearing loss, unspecified
L20.0	Besnier's prurigo
L20.81 - L20.9	Atopic neurodermatitis, flexural eczema, other atopic dermatitis
L23.7	Allergic contact dermatitis due to plants, except food
L24.7	Irritant contact dermatitis due to plants, except food
L25.5	Unspecified contact dermatitis due to plants, except food
L23.0	Allergic contact dermatitis due to metals
L24.81	Irritant contact dermatitis due to metals
L23.9	Allergic contact dermatitis, unspecified cause
L24.9	Irritant contact dermatitis, unspecified cause
L25.9	Unspecified contact dermatitis, unspecified cause
L30.0	Nummular dermatitis
L30.2	Cutaneous autosensitization
L30.8	Other specified dermatitis
L30.9	Dermatitis, unspecified
Q16.1	Congenital absence, atresia and stricture of auditory canal (external)
Q16.4	Other congenital malformations of middle ear
Q16.3	Congenital malformation of ear ossicles
Q17.9	Congenital malformation of ear, unspecified

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply enrollee coverage or provider reimbursement. Consult the enrollee's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal/ state laws.

REFERENCES

1. Ho, EC, Monksfield, P, Egan, E, Reid, A, Proops, D. Bone-anchored hearing aid: patient satisfaction with the Cordelle device. *Otol Neurotol*. 2009;30(6):793-799.
2. Bone-anchored hearing aids. Hayes Directory Web site. <http://www.hayesinc.com>. Published June 3, 2005 [archived on July 3, 2010]. Accessed March 10, 2020.
3. McDermott, AL, Williams, J, Kuo, M, Reid, A, Proops, D. The Birmingham pediatric bone-anchored hearing aid program: a 15-year experience. *Otol Neurotol*. 2009;30(2):178-183.
4. McDermott, AL, Williams, J, Kuo, M, Reid, A, Proops, D. Quality of life in children fitted with a bone-anchored hearing aid. *Otol Neurotol*. 2009b;30(3):344-349.

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MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
4/16/2020	<ul style="list-style-type: none">• Approved by MPC. No changes.
3/26/2019	<ul style="list-style-type: none">• Approved by MPC. Reinstated for non-MCG markets.
3/7/2019	<ul style="list-style-type: none">• Approved by MPC. Retired as part of the MCG go-live.
6/1/2018, 7/6/2017	<ul style="list-style-type: none">• Approved by MPC. No changes.
9/27/2016, 7/9/2015, 8/7/2014, 8/1/2013, 9/6/2012	<ul style="list-style-type: none">• Approved by MPC. Coding changes only.
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
9/1/2011	<ul style="list-style-type: none">• Approved by MPC.