Bone-Anchored (BAHA) and Semi Implantable Hearing Aids

Policy Number: 2013M0023A  Effective Date: January 1, 2014

INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This policy provides information about bone-anchored and semi-implantable hearing aids and their recommended use. Bone-anchored hearing aids (BAHAs) transmit sound vibrations to the inner ear by direct bone transmission through the skull. A titanium screw implanted into the skull allows removable coupling of the sound processor to the bone. Semi-implantable hearing aids consist of an external audio processor that is worn behind the ear or in the ear canal, a receiver that may be housed with the audio processor or implanted, and an electromagnetic transducer. Both devices are intended to improve hearing precision in individuals who have moderate to severe conductive or mixed hearing loss and who cannot use or are dissatisfied with the level of sound perception or quality of sound provided by standard air conduction hearing aids (ACHAs).

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

A. Unilateral or bilateral osseointegrated implants, bone-anchored and semi implantable hearing aid(s) devices, may be considered **MEDICALLY NECESSARY** as an alternative to an air-conduction hearing aid for individuals five years of age and older with a conductive or mixed hearing loss who has one of the following medical conditions and meet at least one audiology criteria:

Medical Conditions (at least one):
- Congenital or surgically induced malformations (e.g., atresia) of the external or middle ear canal
- Severe chronic external otitis or otitis media
- Tumors of the external ear canal and/or tympanic cavity
- Dermatitis of the external ear canal
- Other anatomic or medical conditions that contraindicate the use of an air conduction hearing aid

Audiologic criteria (at least one):
- A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz of better than or equal to 45 dB (OBC and BP100 devices), 55 dB (Intenso device), or 65 dB (Cordele II device).
- For bilateral implantation, patients should meet the above audiology criteria and have a symmetrically conductive or mixed hearing loss as defined by a difference between left and right side bone conduction threshold of less than 10 dB on average measured at 0.5, 1, 2 and 3 kHz (4 kHz for OBC and Ponto Pro), or less than 15 dB at individual frequencies.

B. An semi implantable bone-conduction (bone-anchored) hearing aid may be considered **MEDICALLY NECESSARY** as an alternative to an air-conduction CROS hearing aid in patients 5 years of age and older with single-sided sensorineural deafness and normal hearing in the other ear. The pure tone average air conduction threshold of the normal ear should be better than 20 dB measured at 0.5, 1, 2, and 3 kHz.

C. Replacement parts or upgrades to existing Baha components (e.g., batteries, processor) are considered not medically necessary when the criteria specified in (A) or (B) above are not met or when requested for convenience or to upgrade to newer technology when the current components remain functional.

D. Partially implantable bone conduction hearing systems using magnetic coupling for acoustic transmission (e.g., Otomag Alpha 1 [MJ]) are considered **EXPERIMENTAL OR INVESTIGATIONAL**.
E. Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in patients with bilateral sensorineural hearing loss, are considered **EXPERIMENTAL OR INVESTIGATIONAL**.

**BENEFIT NOTE:**

Bone-Anchored (BAHA) and Semi Implantable Hearing Aid devices are referred to as Hearing Aid, Bone Conduction in the U.S. Food and Drug Administration (FDA) label. The FDA also indicates that this device has substantially equivalent technology as air-conduction hearing aids with digital sound processing. However, Medicare and Medicaid Services (CMS) consider these devices as prosthetics. Therefore, osseointegrated devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare Advantage as prosthetic devices. Thus, Plan needs to review contract language in making decisions about classification. Benefit limitations regarding hearing aids may apply in the Exchange and other products.

**Clinical Considerations:**

- BAHAs utilize an FDA-approved, bone-anchored, bone conduction hearing aid, specifically indicated for individuals five years of age and older.
- The most successful outcomes are obtained when used in adults who suffer from chronic otitis media and mastoids and were unable to tolerate traditional air conduction hearing aids or in whom these were contraindicated due to either recurrent otorrhoea, otitis externa or aural stenosis, and in pediatrics with congenital aural atresia.
- BAHAs avoid the several potential complications of surgical reconstruction of congenital atresia, an operation fraught with difficulty in young children with acceptable results only in expert hands.
- Current techniques of fixture implantation and osseointegration are associated with minimal complication rates. However, the health of the titanium implant and the ultimate success of the BAHA depend heavily upon meticulous surgical care and cleaning of the abutment. However, complications of BAHAs can be considered in two categories: intra-operative and post-operative complications.
- Intraoperative complications are more common in children because most of them have craniofacial abnormalities.
- Magnetic resonance imaging (MRI) is contraindicated in patients using Semi-Implantable Electromagnetic Hearing Aids devices because it produces linear and rotational forces that may dislodge the implant and damage surrounding tissue. The FDA recommends removing the implant if MRI is medically necessary. Electrosurgery near the implant, diathermy over the implant, or electroconvulsive therapy in a patient with the implant are also not advised due to potential damage to the implant or the patient’s hearing.
- In patients being considered for implantable bone-conduction (bone-anchored) hearing aid(s), skull bone quality and thickness should be assessed for adequacy to ensure implant stability. Additionally, patients (or caregivers) must be able to perform proper hygiene to prevent infection and ensure the stability of the implants and percutaneous abutments.
**BACKGROUND:**

More than 28 million Americans suffer from congenital or acquired hearing loss. Hearing loss can be classified as conductive, sensorineural, or mixed hearing loss. Conductive hearing loss involves the external and middle ear and is due to mechanical or physical blockage of sound as a result of excessive cerumen, a punctured eardrum, birth/congenital defects such as congenital aural atresia (CAA), ear infections or heredity. In sensorineural or "nerve" hearing loss, the auditory cranial nerve or part of the bone of the inner ear is damaged due to birth-related condition, long-term viral or bacterial infections, trauma, exposure to loud noises, the use of certain drugs, fluid buildup in the middle ear, or a benign tumor in the inner ear (acoustic neuroma). Mixed hearing loss is conductive hearing loss coupled with sensorineural hearing loss. Normal range or no impairment of hearing occurs at 0 to 20 dB threshold. The American Speech-Language-Hearing Association (ASLHA, 2010) defines the degree (severity) of hearing loss (HL) as:

- mild (20 to 40 dB),
- moderate (40 to 60 dB),
- severe (60 to 80 dB), and
- profound (greater than or equal to 80 dB)

Permanent hearing loss is often treated with hearing aids. Conventional external hearing aids consist of a microphone to detect sounds in the environment, a battery-powered amplifier to increase sound volume, and a small-diameter tube that functions as a sound pressure conduit. Sound received in the microphone is processed by the amplifier and transmitted by the sound pressure conduit into the ear canal as sound pressure, which vibrates the eardrum, ossicles, and inner ear fluids. Over the last decade, conventional hearing aids have evolved with improvements in analog and digital processing. Despite improvements, conventional hearing aids continue to be limited by problems that lead to nonuse including occlusive effects, acoustic feedback, sound distortion, infection, chronic irritation, discomfort, frequent battery changes and maintenance, lifestyle restrictions, and cosmesis.

Implantable hearing devices, such as cochlear implants (CIs), bone-anchored hearing aids (BAHAs), and middle ear implants (MEIs), may offer alternatives for individuals who will not use or do not derive sufficient benefit from conventional hearing aids. These devices employ different designs to treat a specific type and degree of hearing loss.

BAHAs transmit sound directly to the skull or ossicles instead of through an amplifier as in conventional hearing aids. BAHAs consist of a titanium fixture which is implanted behind the ear in the temporal bone and protrudes through the skin, and an external sound processor connects to the implanted fixture. The microphone of the sound processor detects sound vibrations and transfers them to the cochlea by direct bone conduction. The difference between the standard bone conduction hearing aid and the bone-anchored hearing aid is direct stimulation of the bone instead of stimulation through the skin.

MEIs generally have been used in adults with moderate to severe SNHL who are noncompliant with, or do not obtain sufficient benefit from, conventional hearing aids. MEIs are broadly divided into semi-implantable or fully implantable piezoelectric or electromagnetic hearing systems. Despite different designs, all MEIs work by stimulating the ossicles, thereby enhancing signals received by cochlear hair cells. Semi-implantable electromagnetic hearing aids consist of an audio processor unit that is worn behind the ear or in the ear canal and houses a microphone, sound processor, and battery; a receiver unit that may be housed with the audio processor or implanted; and an electromagnetic transducer that is implanted so that
its tip contacts the ossicles or is close to a magnet implanted on the ossicles. The microphone detects, amplifies, and converts sounds into electric currents which are successively, manipulated by the sound processor, transmitted to the receiver coil, and conveyed to the electromagnetic transducer. This transducer converts the electric currents into a magnetic field that vibrates the ossicles, either by direct contact with the ossicles or by acting on (attracting and repelling) a magnet implanted on the ossicles.

Currently, three semi-implantable electromagnetic hearing devices are commercially available in the United States and/or Europe. These are the Vibrant® Soundbridge™ System (MedEl GmbH); the Maxum™ System (Ototonix), originally marketed under the name Soundtec® Direct System™ (Ototonix); and the Semi-Implantable Middle Ear Transducer (MET) Ossicular Stimulator System (Otologics LLC).

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):

Bone-Anchored Hearing Aids (BAHAs):

There are four BAHA® sound processors for use with the BAHA auditory osseointegrated implant system manufactured by Cochlear Americas (Englewood, CO) that have received 510(k) clearance from the U.S. Food and Drug Administration (FDA):

- BAHA® Cordelle II™
- BAHA® Divino™
- BAHA® Intenso™ (digital signal processing)
- BAHA® BP100™

The U.S. Food and Drug Administration (FDA) approved the BAHA system for the following indications:

- Patients who have conductive or mixed hearing loss and can still benefit from sound amplification
- Patients with bilaterally symmetric conductive or mixed hearing loss, may be implanted bilaterally
- Patients with sensorineural deafness in one ear and normal hearing in the other (i.e., single-sided deafness, SSD)
- Patients who are candidates for an air-conduction contralateral routing of signals (AC CROS) hearing aid but who cannot or will not wear an AC CROS device.

- In 1995, the FDA granted approval to Nobelpharm USA to market the BRÅNEMARK Bone-Anchored Hearing Aid (BAHA®) System, which is manufactured by Entific Medical Systems for adult patients with malformations of the external ear, chronically draining ear, a pure tone threshold hearing loss of ≥ 45 decibels (dB), and/or inability or unwillingness to use an air conduction hearing aid. In 1999, this approval was extended for use in children 5 years of age or older. In 2002, the BAHA® System was approved for single-sided deafness due to sensorineural deafness (Entific Medical Systems, 2005; FDA, 2005).

- Another BAHA, the Xomed Audiant™ Bone Conductor (Xomed, Inc.), was approved by the FDA in 1986 but is no longer on the market (FDA, 2005).

- In May 2011, the FDA cleared a modified sound processor, the BAHA BP110 Power as a
substantially equivalent sound processor to the predicate BAHA Intenso.

- The Headband/Softband for BAHA received FDA 510(k) clearance in October 2000 as substantially equivalent to devices already on the market. With this application, there is no implantation surgery. The sound processor is attached to the head using either a hard or soft headband. The amplified sound is transmitted transcutaneously to the bones of the skull for transmission to the cochlea. The BAHA® Softband™ received FDA clearance in 2002 for use in children younger than the age of 5 years. As this application has no implanted components, it is not addressed in the policy.

- In November 2008, the device “OBC Bone Anchored Hearing Aid System” (Oticom Medical, Kongebakken, Denmark) was cleared by the U.S. Food and Drug Administration (FDA) for marketing through the 510(k) process. Subsequently, additional bone conduction hearing systems have received 510(k) marketing clearance from the FDA including Otomag (Sophono, Inc., Boulder, CO) and Ponto (Oticom Medical). The Ponto Pro processor can be used with the Oticon or BAHA implants. In May 2011, Sophono, Inc. and Oticom Medical partnered to receive 510(k) marketing clearance from the FDA for the Otomag Alpha I(M), a partially implantable bone conduction hearing system. All of these devices were determined to be substantially equivalent to existing devices (e.g., the Xomed Audiant, which was FDA cleared for marketing in 1986 but is no longer available). They share similar indications as the Cochlear Americas BAHA devices.

**Semi-Implantable Electromagnetic Hearing Aid Devices:**

Currently, there are only two semi-implantable electromagnetic hearing aid devices (product code, MPV) approved by the FDA.

- Vibrant Soundbridge System (Premarket Approval [PMA] number, P990052), which was approved on August 31, 2000.
- Maxum System (PMA number, 9010023), which was approved by the FDA on September 7, 2001.
- The semi-implantable Middle Ear Transducer (MET) Ossicular Stimulator System (Otologics) is commercially available in Europe for treating moderate to severe SNHL in adults (Tringali et al., 2010) but is not approved by the FDA (CDRH, 2011).

2. **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):**

100 - Hearing Aids and Auditory Implants (Rev. 39; Issued: 11-10-05; Effective: 11-10-05; Implementation: 12-12-05).

Section 1862(a)(7) of the Social Security Act states that no payment may be made under part A or part B for any expenses incurred for items or services “where such expenses are for . . . hearing aids or examinations therefore. . . .” This policy is further reiterated at 42 CFR 411.15(d) which specifically states that “hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids” are excluded from coverage.

3. **MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):**

CLINICAL EVIDENCE:

Summary:
**Bone-Anchored Hearing Aids:** The available evidence for unilateral or bilateral implantable boneconduction (bone-anchored) hearing aid(s) consists of observational studies that report pre-post differences in hearing parameters after treatment with BAHA. While this evidence is not ideal, it is sufficient to demonstrate improved net health outcome for patients 5 years of age or older in certain situations. The evidence supports the use of these devices in patients with conductive or mixed hearing loss who meet other medical and audiologic criteria. For patients with single-sided sensorineural deafness, a binaural hearing benefit may be provided by way of contralateral routing of signals to the hearing ear. There is evidence that bilateral devices improve hearing to a greater degree than do unilateral devices. Bone-anchored hearing aids may be considered as an alternative to air-conduction devices in these patients and therefore, these devices may be considered medically necessary in these situations.

**Semi-Implantable Electromagnetic Hearing Aid Devices:** The available evidence from the studies indicate that, compared with unaided hearing, the Vibrant Soundbridge System improves hearing thresholds and speech perception. This device appears to improve patient satisfaction; however, evidence is conflicting about the impact on hearing thresholds and speech perception compared with conventional hearing aids.

APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S9128</td>
<td>Speech therapy, in the home, per diem</td>
</tr>
<tr>
<td>S2230</td>
<td>Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear</td>
</tr>
<tr>
<td>V508-V5299</td>
<td>Hearing Services</td>
</tr>
<tr>
<td>L8690</td>
<td>Auditory osseointegrated device, includes all internal and external components</td>
</tr>
<tr>
<td>L8691</td>
<td>Auditory osseointegrated device, external sound processor, replacement</td>
</tr>
<tr>
<td>L8692</td>
<td>Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment [excluded under plans that exclude coverage of hearing aids]</td>
</tr>
<tr>
<td>L8693</td>
<td>Auditory osseointegrated device abutment, any length, replacement only</td>
</tr>
<tr>
<td>G0153</td>
<td>Services performed by a qualified speech-language pathologist in the home health or hospice setting, each 15 minutes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>160.1</td>
<td>Malignant neoplasm of auditory tube, middle ear, and mastoid air cells</td>
</tr>
<tr>
<td>171.0</td>
<td>Malignant neoplasm of head, face and neck</td>
</tr>
<tr>
<td>173.2</td>
<td>Malignant neoplasm of skin of ear and external auditory canal</td>
</tr>
<tr>
<td>ICD-10 Codes</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>212.0</td>
<td>Benign neoplasm of nasal cavities, middle ear, and accessory sinuses</td>
</tr>
<tr>
<td>215.0</td>
<td>Benign neoplasm of head, face, and neck</td>
</tr>
<tr>
<td>216.2</td>
<td>Benign neoplasm of ear and external auditory canal</td>
</tr>
<tr>
<td>232.2</td>
<td>Carcinoma in situ of ear and external auditory canal</td>
</tr>
<tr>
<td>277.5</td>
<td>Hunter’s Syndrome</td>
</tr>
<tr>
<td>380.32</td>
<td>Acquired deformities of auricle or pinna [surgically induced malformations of external ear canal or middle ear]</td>
</tr>
<tr>
<td>381.10</td>
<td>Chronic serous otitis media, simple or unspecified [severe]</td>
</tr>
<tr>
<td>381.3</td>
<td>Other and unspecified chronic nonsuppurative otitis media [severe]</td>
</tr>
<tr>
<td>382.2</td>
<td>Other atopic dermatitis and related conditions</td>
</tr>
<tr>
<td>382.9</td>
<td>Contact dermatitis and other eczema [external ear/hypersensitivity reactions]</td>
</tr>
<tr>
<td>387.0 - 387.9</td>
<td>Otosclerosis [causing hearing loss in persons who cannot undergo stapedectomy]</td>
</tr>
<tr>
<td>389.00 - 389.08</td>
<td>Conductive hearing loss</td>
</tr>
<tr>
<td>389.10</td>
<td>Sensorineural hearing loss, unspecified</td>
</tr>
<tr>
<td>389.11</td>
<td>Sensory hearing loss</td>
</tr>
<tr>
<td>389.12</td>
<td>Neural hearing loss</td>
</tr>
<tr>
<td>389.14</td>
<td>Central hearing loss</td>
</tr>
<tr>
<td>389.15</td>
<td>Sensorineural hearing loss, unilateral</td>
</tr>
<tr>
<td>389.18</td>
<td>Sensorineural hearing loss of combined types</td>
</tr>
<tr>
<td>389.2 – 389.22</td>
<td>Mixed conductive and sensorineural hearing loss</td>
</tr>
<tr>
<td>691.8</td>
<td>Other anomalies of external ear with impairment of hearing [congenital malformations of external ear canal]</td>
</tr>
<tr>
<td>692.0 - 692.6, 692.81</td>
<td>Contact dermatitis and other eczema [external ear/hypersensitivity reactions]</td>
</tr>
<tr>
<td>692.83 - 692.9</td>
<td>Anomaly of middle ear, except ossicles [congenital malformations of middle ear]</td>
</tr>
<tr>
<td>744.02</td>
<td>Anomaly of middle ear, except ossicles [congenital malformations of middle ear]</td>
</tr>
<tr>
<td>744.03</td>
<td>Other anomalies of ear ossicles [congenital malformations of middle ear]</td>
</tr>
<tr>
<td>744.3</td>
<td>Unspecified anomaly of ear [congenital malformations of external ear canal or middle ear]</td>
</tr>
<tr>
<td>745.4</td>
<td>Hemifacial microsomi</td>
</tr>
<tr>
<td>755.1x*</td>
<td>Syndactylia</td>
</tr>
<tr>
<td>755.55</td>
<td>Pfeiffer’s disease</td>
</tr>
<tr>
<td>756.0</td>
<td>Crouzon’s disease</td>
</tr>
<tr>
<td>756.0*</td>
<td>Treacher Collins</td>
</tr>
<tr>
<td>759.9</td>
<td>Thalamoid embryopathy</td>
</tr>
</tbody>
</table>

* The x represents a range of codes; it is dependent on the specific diagnosis.
<table>
<thead>
<tr>
<th>H90.6</th>
<th>Mixed conductive and sensorineural hearing loss, bilateral</th>
</tr>
</thead>
<tbody>
<tr>
<td>H90.7</td>
<td>Mixed conductive and sensorineural hearing loss, unilateral with unrestricted hearing on the contralateral side</td>
</tr>
<tr>
<td>H90.8</td>
<td>Mixed conductive and sensorineural hearing loss, unspecified</td>
</tr>
</tbody>
</table>

CPT® is a registered trademark of the American Medical Association.

**REFERENCES:**


POLICY HISTORY:

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/25/2013</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
</tr>
<tr>
<td>11/15/2013</td>
<td>Published to ucare.org</td>
</tr>
</tbody>
</table>