MEDICAL POLICY – 7.01.547

Implantable Bone Conduction and Bone-Anchored Hearing Aids

BCBSA Ref. Policy: 7.01.03

Effective Date: May 1, 2019
Last Revised: April 2, 2019
Replaces: 7.01.03

RELATED MEDICAL POLICIES:
1.01.528 Hearing Aids (Excludes Implantable Devices)
7.01.05 Cochlear Implant
7.01.84 Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | APPENDIX | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

A typical hearing aid amplifies or increases sounds. If there are problems with the outer or middle ear, those problems could interfere with the sound waves traveling to the inner ear. A bone anchored hearing aid bypasses the outer and middle ear. A sound processor is worn near the ear and connects to a small implant. The implant is connected to the skull bone. The sound processor gathers sounds in the air and converts them into vibrations. The vibrations are sent through the implant into the skull bone. The skull bone naturally sends the vibrations to the inner ear. The inner ear is able to switch the vibrations into nerve signals, which the brain interprets as sound. This policy describes when bone anchored hearing aids may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Subject</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Unilateral conductive or mixed hearing loss  | A unilateral, fully or partially implantable bone conduction (bone-anchored) hearing aid may be considered medically necessary as an alternative to an air-conduction hearing aid in patients 5 years of age and older with a conductive or mixed hearing loss when ONE of the following medical criteria is present:  
  • Congenital or surgically induced malformations (eg, atresia) of the external ear canal or middle ear  
  OR  
  • Chronic external otitis or otitis media  
  OR  
  • Tumors of the external canal and/or tympanic cavity  
  OR  
  • Dermatitis of the external canal  
  AND the following audiologic criterion is met:  
  • A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz (same as 500, 1,000, 2,000, and 3,000 Hz) of better than or equal to 45 dB (OBC and BP100 devices), 55 dB (Intenso™ device) or 65 dB (Cordele II™ device). |
| Bilateral conductive or mixed hearing loss    | Bilateral fully or partially implantable bone conduction (bone-anchored) hearing aid(s) may be considered medically necessary as an alternative to an air-conduction hearing aid in patients 5 years of age and older when the following criteria are met:  
  • A symmetrically conductive or mixed hearing loss is present as defined by:  
    o 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 (same as 500, 1,000, 2,000, and 3,000 Hz) (4 kHz for OBC and Ponto™ Pro devices)  
    OR  
    o Less than 15 dB at individual frequencies; |
<table>
<thead>
<tr>
<th>Subject</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Single-sided sensorineural deafness and normal hearing in the other ear | AND the following audiologic criterion is met:  
  - 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). |
| Use of non-implanted bone-conduction (bone-anchored) hearing aids  | An implantable bone-conduction (bone-anchored) hearing aid may be considered medically necessary as an alternative to an air-conduction contralateral routing of signal (CROS) hearing aid when the following criteria are met:  
  - The patient is 5 years of age or older  
  - The patient has single-sided sensorineural deafness  
  - The patient has 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 (same as 500, 1,000, 2,000, and 3,000 Hz). |

<table>
<thead>
<tr>
<th>Subject</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other uses of implanted bone-conduction/bone-anchored hearing aids</td>
<td>The use of implantable bone-conduction (bone-anchored) hearing aids is considered investigational when the criteria above are not met, including use in patients with bilateral sensorineural hearing loss.</td>
</tr>
</tbody>
</table>

**Patient Characteristics**

**Implanted bone-conduction (bone-anchored) hearing aid(s)**

Bone-anchored hearing solutions may also be known as osseointegrated hearing implants. Assessing patients prior to surgery for skull bone quality and thickness adequacy will help to
**Patient Characteristics**

Ensure stability of the implanted abutment in the bone behind the ear. Additionally, patients (or caregivers) must be trained to properly clean the implanted and external components to prevent infection and safeguard the skin integrity at the site where the sound processor attaches to the skull. Surgical implantation of the bone anchored hearing aid (BAHA®) device is not FDA approved for children younger than 5 years of age.

**Non-implanted use of a bone-conduction (bone-anchored) hearing aid(s)**

Unique clinical circumstances may justify individual consideration for wearing the bone-conduction sound processor on the surface of the skull with a headband or softband before 5 years of age. Consideration for each request for a non-implanted bone conduction device should be based on a clinical review of applicable medical records to verify the medical necessity criteria listed in this policy are met. (See Benefit Application).

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**Reasonable Useful Life Expectancy for BAHA Parts**

<table>
<thead>
<tr>
<th>Replacement Parts</th>
<th>Life Expectancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batteries</td>
<td>72 per 6 months</td>
</tr>
<tr>
<td>Headband</td>
<td>1 per year</td>
</tr>
<tr>
<td>Processor</td>
<td>1 per 5 years</td>
</tr>
</tbody>
</table>

**Documentation Requirements**

The medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:

- The type of hearing loss for member who is 5 years old or older
- Any inner or outer ear conditions that prevent use of a conventional air-conductive hearing aid
- Result of audiologic test (hearing test) showing the level of hearing loss

**Note:** Cochlear implants, used for the treatment of severe to profound deafness are addressed in a separate medical policy. (See Related Policies)
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>69710</td>
<td>Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone</td>
</tr>
<tr>
<td>69711</td>
<td>Removal or repair of electromagnetic bone conduction hearing in temporal bone</td>
</tr>
<tr>
<td>69714</td>
<td>Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy</td>
</tr>
<tr>
<td>69715</td>
<td>Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy</td>
</tr>
<tr>
<td>69717</td>
<td>Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy</td>
</tr>
<tr>
<td>69718</td>
<td>Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy</td>
</tr>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>L8625</td>
<td>External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each</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 Note: this code describes the non-implanted use of the bone conduction sound processor.</td>
</tr>
<tr>
<td>L8693</td>
<td>Auditory osseointegrated device abutment, any length, replacement only</td>
</tr>
<tr>
<td>L8694</td>
<td>Auditory osseointegrated device, transducer/actuator, replacement only, each</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**Related Information**
Consideration of Age

The age stated in this policy for which implantable bone conduction hearing aids may be considered medically necessary is 5 years and older. This is based on the FDA approval. Surgical implantation of the BAHA® device is not FDA approved for children younger than 5 years of age. The age stated in this policy for which a sound processor worn on the skull may be considered medically necessary is age 5 and younger. This is based on the nonsurgical/transcutaneous application of the BAHA® processor using a headband or softband which received FDA approval for use in children under the age of 5 years.

Benefit Application

A bone-conduction (bone-anchored) hearing aid is a surgically implantable device used to treat a medical condition. The device and implantation surgery should be reimbursed under the medical benefit.

Benefit limitations regarding hearing aids may apply to these devices, specifically when the Implantable Bone-Conduction and Bone-Anchored Hearing Aid (BAHA®) device is used transcutaneously (on the surface of the skin of the head) held in place by a headband or softband and not implanted.

Evidence Review

Description

Sensorineural, conductive, and mixed hearing loss may be treated with various devices, including conventional air-conduction or bone-conduction external hearing aids. Air-conduction hearing aids may not be suitable for patients with chronic middle ear and ear canal infections, atresia of the external canal, or an ear canal that cannot accommodate an ear mold. Bone-conduction hearing aids may be useful for individuals with conductive hearing loss, or (if used with contralateral routing of signal), for unilateral sensorineural hearing loss. Implantable, bone-anchored hearing aids (BAHAs) that use a percutaneous or transcutaneous connection to a sound processor have been investigated as alternatives to conventional bone-conduction hearing aids for patients with conductive or mixed hearing loss or for patients with unilateral single-sided sensorineural hearing loss.
In children under 5 years of age the transcutaneous use of the BAHA® has shown positive outcomes in small studies. The bone conduction-type hearing aid is held against the skin behind the ear, or at another bony location of the skull using a strap, headband or softband. The headband is soft plastic while the softband is soft elastic with a plastic disc-like snap connector either modeled or sewn into the band. A BAHA® sound processor is attached to the plastic connector and the band/headband is adjusted to the size of the individual's head and is secured with a Velcro® fastener (Velcro USA Inc., Manchester, NH) (see Appendix).

Background

Hearing Loss

Hearing loss is described as conductive, sensorineural, or mixed, and can be unilateral or bilateral. Normal hearing detects sound at or below 20 decibels (dB). The American Speech-Language Hearing Association has defined the degree of hearing loss based on pure-tone average detection thresholds as mild (20 - 40 dB), moderate (40 - 60 dB), severe (60 - 80 dB), and profound (≥ 80 dB). Pure-tone average is calculated by averaging hearing sensitivities (ie, the minimum volume that a patient hears) at multiple frequencies (perceived as pitch), typically within the range of 0.25-8 kHz.

Sound amplification using an air-conduction (AC) hearing aid can provide benefit to patients with sensorineural or mixed hearing loss. Contralateral routing of signal (CROS) is a system in which a microphone on the affected side transmits a signal to an AC hearing aid on the normal or less affected side.

Treatment

External bone-conduction hearing devices function by transmitting sound waves through the bone to the ossicles of the middle ear. The external devices must be applied close to the temporal bone, with either a steel spring over the top of the head or a spring-loaded arm on a pair of spectacles. These devices may be associated with either pressure headaches or soreness.

A bone-anchored implant system combines a vibrational transducer coupled directly to the skull via a percutaneous abutment that permanently protrudes through the skin from a small titanium implant anchored in the temporal bone. The system is based on osseointegration through which living tissue integrates with titanium in the implant over 3 to 6 months, conducting amplified and processed sound via the skull bone directly to the cochlea. The lack of intervening skin
permits the transmission of vibrations at a lower energy level than required for external bone-conduction hearing aids. Implantable bone-conduction hearing systems are primarily indicated for people with conductive or mixed sensorineural and conductive hearing loss. They may also be used with CROS as an alternative to an AC hearing aid for individuals with unilateral sensorineural hearing loss.

A bone conduction processor can also be used with a softband or headband. The sound processor is pressed against the head, usually behind the ear. With this application, there is no titanium peg implantation surgery. The amplified sound is transmitted transcutaneously to the cochlea using the skull bones, bypassing the outer and middle ear. In children under 5 years of age, this non-implanted use of the processor may be part of the trial period before surgery.

Partially implantable magnetic bone-conduction hearing systems, also referred to as transcutaneous bone-anchored systems, are an alternative to the bone-conduction hearing systems that connect to bone percutaneously via an abutment. With this technique, acoustic transmission occurs transcutaneously via magnetic coupling of the external sound processor and the internally implanted device components. The bone-conduction hearing processor contains magnets that adhere externally to magnets implanted in shallow bone beds with the bone-conduction hearing implant. Because the processor adheres magnetically to the implant, there is no need for a percutaneous abutment to physically connect the external and internal components. To facilitate greater transmission of acoustics between magnets, skin thickness must be reduced to 4-5 mm over the implant when it is surgically placed.

**Summary of Evidence**

For individuals who have conductive or mixed hearing loss who receive an implantable bone-anchored hearing aid (BAHA) with a percutaneous abutment or a partially implantable BAHA with transcutaneous coupling to the sound processor, the evidence includes observational studies that have reported pre-post differences in hearing parameters after treatment with BAHAs. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. No prospective trials were identified. Observational studies reporting on within-subjects changes in hearing have generally reported hearing improvements with the devices. Given the objectively measured outcomes and the largely invariable natural history of hearing loss in individuals who would be eligible for an implantable bone-conduction device, the demonstrated improvements in hearing after device placement can be attributed to the device. Studies of partially implantable BAHAs have similarly demonstrated within-subjects improvements in hearing. The single-arm studies have shown improvements in hearing in the device-aided state. No direct comparisons other than within-individual comparisons with
external hearing aids were identified, but, for individuals unable to wear an external hearing aid, there may be few alternative treatments. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive a fully or partially implantable BAHA with the contralateral routing of signal, the evidence includes a randomized controlled trial (RCT), multiple prospective and retrospective case series, and a systematic review. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. Single-arm case series, with sample sizes ranging from 9 to 180 patients, have generally reported improvements in patient-reported speech quality, speech perception in noise, and satisfaction with bone conduction devices with contralateral routing of the signal. However, a well-conducted systematic review of studies comparing bone-anchored devices with hearing aids using contralateral routing of signal found no evidence of improvement in speech recognition or hearing localization. The single RCT included in the systematic review was a pilot study enrolling only 10 patients and, therefore, does not provide definitive evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 1 below.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01858246</td>
<td>A Randomised Controlled Trial Comparing Bone Anchored Hearing Aid With Bonebridge</td>
<td>60</td>
<td>Dec 2017</td>
</tr>
<tr>
<td>NCT02092610</td>
<td>Long Term Stability, Survival and Tolerability of a (Novel) Baha® Implant System</td>
<td>77</td>
<td>Mar 2015</td>
</tr>
<tr>
<td>NCT01264510</td>
<td>The Evaluation of the Effectiveness of Bone-anchored Hearing Aids (Baha) in Patients With Conductive or Mixed Hearing Loss, or Unilateral Deafness</td>
<td>150</td>
<td>Aug 2015</td>
</tr>
<tr>
<td>NCT02022085</td>
<td>Post-market Clinical Follow-up of a Magnetic Bone Conduction Implant (Cochlear BAHA Attract System)</td>
<td>2</td>
<td>Nov 2017</td>
</tr>
</tbody>
</table>
Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 specialty societies and 3 academic medical centers (one of which provided 4 responses and one of which provided 3 responses) while this policy was under review in 2016. Input focused on the categorization of partially implantable bone-anchored devices relative to fully implantable devices. There was a strong consensus that partially implantable devices are considered an evolution of earlier devices, and that direct trials comparing the two are not necessary.

Practice Guidelines and Position Statements

American Academy of Otolaryngology-Head and Neck Surgery

In 2016, The American Academy of Otolaryngology-Head and Neck Surgery updated its position statement on the use of implantable hearing devices.79 It states that the Academy “considers bone conduction hearing devices, including implantation of a percutaneous or transcutaneous device and use of a bone conduction oral appliance or bone conduction scalp device to be acceptable, and in many cases preferred, procedures in the treatment of conductive or mixed hearing loss and single-sided deafness when performed by a qualified otolaryngologist-head and neck surgeon”.

Medicare National Coverage

There is no national coverage determination. The Medicare Benefit Policy Manual references hearing aids and auditory implants, stating that hearing aids are excluded from coverage, including air-conduction and bone-conduction devices.80 However, devices producing the
perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be used. Along with cochlear and auditory brainstem implants, the benefits manual specifically refers to osseointegrated implants as prosthetic devices. In 2014, Medicare clarified its hearing aid coverage to state that “certain auditory implants, including cochlear implants, brain stem implants, and osseointegrated implants, do not meet the definition of hearing aids that are excluded from coverage.”

Regulatory Status

Several implantable bone-conduction hearing systems have been approved by the US Food and Drug Administration for marketing through the 510(k) process (see Table 2).

Table 2. Implantable Bone-Conduction Hearing Systems Approved by the US Food and Drug Administration

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baha® Auditory Osseointegrated Implant System</td>
<td>Cochlear™ (formerly Cochlear™ Americas)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baha® 5</td>
<td></td>
<td>Mar 2015</td>
<td>K142907</td>
</tr>
<tr>
<td>Baha® Cordelle II</td>
<td></td>
<td>Apr 2008</td>
<td>K080363</td>
</tr>
<tr>
<td>Baha Divino®</td>
<td></td>
<td>Aug 2004</td>
<td>K042017</td>
</tr>
<tr>
<td>Baha Intenso® (digital signal processing)</td>
<td></td>
<td>Aug 2008</td>
<td>K081606</td>
</tr>
<tr>
<td>Baha® BP100</td>
<td></td>
<td>Jun 2009</td>
<td>K090720</td>
</tr>
<tr>
<td>Baha® 4 (upgraded from the BP100)</td>
<td></td>
<td>Sep 2013</td>
<td>K132278</td>
</tr>
<tr>
<td>OBC Bone-Anchored Hearing Aid System</td>
<td>Oticon Medical</td>
<td>Nov 2008</td>
<td>K112053</td>
</tr>
<tr>
<td>Ponto Bone-Anchored Hearing System</td>
<td>Oticon Medical</td>
<td>Sep 2012</td>
<td>K121228</td>
</tr>
</tbody>
</table>

The FDA cleared these systems for use in children ages 5 years and older and adults 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 1 ear and normal hearing in the other (ie, single-sided deafness);

Patients who are candidates for an AC CROS hearing aid but who cannot or will not wear an AC CROS device.

Baha sound processors can be used with the Baha® Softband™. With this application, there is no implantation surgery. The sound processor is attached to the head using a hard or soft headband. The amplified sound is transmitted transcutaneously to the cochlea via the bones of the skull. In 2002, the Baha® Softband™ was cleared for marketing by FDA for use in children younger than 5 years.

The FDA also cleared two partially implantable magnetic bone-conduction devices for marketing through the 510(k) process (see Table 3).

### Table 3. Partially Implantable Magnetic Bone-Conduction Devices Approved by the US Food and Drug Administration

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otomag® Bone-Conduction/Magnetic Implant System</td>
<td>Medtronic (Formerly Sophono)</td>
<td>Nov 2013</td>
<td>K132189</td>
</tr>
<tr>
<td>Sophono™ Alpha 2 MPO™</td>
<td>Medtronic (Formerly Sophono)</td>
<td>June 2016</td>
<td>K153391</td>
</tr>
<tr>
<td>Cochlear Baha® Attract System</td>
<td>Cochlear™ (formerly Cochlear™ Americas)</td>
<td>Nov 2013</td>
<td>K131240</td>
</tr>
</tbody>
</table>

The Bonebridge™ (MED-EL, Innsbruck, Austria) is another partially implantable bone-conduction implant that is considered an active transcutaneous device. It has been cleared for marketing in Europe but has not received FDA approval for use in the United States.

The SoundBite™ Hearing System (Sonitus Medical, San Mateo, CA) is an intraoral bone-conducting hearing prosthesis that consists of a behind-the-ear microphone and an in-the-
mouth hearing device. In 2011, it was cleared for marketing by FDA through the 510(k) process for indications similar to the Baha. However, the manufacturer, Sonitus Medical, closed in 2015.

FDA product code (for bone-anchoring hearing aid): LXB. FDA product code (for implanted bone-conduction hearing aid): MAH.

References


Appendix

Figure 1.
Implanted used of BAHA

Figure 1 source: http://emedicine.medscape.com/article/1604065-overview Accessed April 2019

Figure 2.
Transcutaneous use of BAHA with Softband

Figure 2 source: http://www.cochlear.com/wps/wcm/connect/uk/home/support/baha-system/connections/softband Accessed April 2019

History
<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/09/12</td>
<td>New policy. Policy includes statement about medical necessity criteria for use of BAHA with headband or softband for children less than 5 years of age; that was not addressed in the BC policy. A table of frequency of BAHA replacement parts is included in the benefit application section. This policy replaces 7.01.03.</td>
</tr>
<tr>
<td>03/08/13</td>
<td>Replace policy. Updated with literature review and references renumbered. Policy statements unchanged.</td>
</tr>
<tr>
<td>03/25/14</td>
<td>Replace policy. Added &quot;magnetic&quot; and &quot;BAHA Attract&quot; to last investigational policy statement. Clarified Benefit Application statement. Rationale updated with literature review through February 2014. Simplified Medicare National Coverage statement. References 3, 25, 34 added; others renumbered/removed. In appendix, revised figures 1-2, added source hyperlinks. Policy statement changed as noted. ICD-9 and ICD-10 codes removed from the policy; these are not utilized in adjudication and were informational only.</td>
</tr>
<tr>
<td>05/01/17</td>
<td>Annual Review, changes approved April 11, 2017. Policy updated with literature review through December 20, 2016; references 23, 37, 53, 57, 59-61, and 69 added. Investigational statement for partially implantable devices is removed. Evaluating the BoneBridge implant as it is not currently cleared for marketing in the USA.</td>
</tr>
<tr>
<td>10/24/17</td>
<td>Policy moved to new format; no change to policy statements.</td>
</tr>
<tr>
<td>05/01/18</td>
<td>Annual Review, approved April 18, 2018. Policy updated with literature review through December 2017; no references added. Added HCPCS code L8694. Policy statement unchanged.</td>
</tr>
<tr>
<td>09/01/18</td>
<td>Minor update. Re-added Consideration of Age information; it was inadvertently removed in a previous update.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit.
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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  - Qualified interpreters
  - Information written in other languages

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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):
يتم منح هذا الإشعار معلومات هامة. قد يحتوي هذا الإشعار معلومات مهمة بخصوص طلبك أو العملية التي تتطلب الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تأثيرات معينة. اتصل بمكتبك المحلي للمعلومات والمسميات للحصول على تفاصيلك المعيشية أو المساعدة في دفع الكفيل. يحق لك الحصول على هذه المعلومات والمسميات بلجان دون تكلفة إضافية.
Call 800-722-1471 (TTY: 800-842-5357)

Italiano (Italian):

Other Languages:
- Arabic
- Dutch
- French
- German
- Hebrew
- Spanish
- Russian
- Chinese
- Japanese
- Korean
- Portuguese
- Tagalog
- Vietnamese

Get help by calling 800-722-1471 (TTY: 800-842-5357) or by using the link provided in the notice. You can also file a complaint with the Department of Health and Human Services, Office for Civil Rights, at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf.
Japanese (Japanese):
この通知には重要な情報が含まれています。この通知には、Premera Blue Crossの申請または補償範囲に関する重要な情報が含まれている場合があります。

この通知に記載されている可能性がある重要な日を確認してください。健康保険や無料サポートを維持するには、特定の期限までに行動を
取らないとならない場合があります。ご自身の言語による情報とサポート
が無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에
관하여 그리고 Premera Blue Cross를 통한 커버리지에 관한 정보를
포함하고 있습니다. 본 통지서는 책임이 되는 날짜들이 있을 수 있습니다。
귀하의 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기
위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다。
귀하의 이러한 정보의 정도를 귀하의 연금에 비용 부담없이 얻을 수 있는
관리가 있습니다。800-722-1471 (TTY: 800-842-5357)로 전화하십시오。

Polski (Polish):
To ogłoszenie może zawierać ważne informacje. To ogłoszenie może
zawierać ważne informacje odnośnie Państwa wniosków lub zakresu
świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na
kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie
przekroczyć terminów w przypadku utraty polisy ubezpieczeniowej lub
promocji związanej z kosztami. Macie Państwo prawo do bezpłatnej
informacji we własnym języku. Zadzwoncie pod 800-722-1471
(TTY: 800-842-5357).

Português (Portuguese):
 Este aviso contém informações importantes. Este aviso poderá conter
informações importantes a respeito de sua aplicação ou cobertura por meio
do Premera Blue Cross. Poderão existir datas importantes neste aviso.
Talvez seja necessário que você tome providências dentro de
determinados prazos para manter sua cobertura de saúde e ajuda de
custos. Você tem o direito de obter esta informação e ajuda em seu idioma

Română (Romanian):
Prezenta notificare conține informații importante. Această notificare
poate conține informații importante privind cererea sau acoperirea asigurării
dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie
în această notificare. Este posibil să fie nevoie să acționați până la
anumite termene limitare pentru a vă menține acoperirea asigurării de sănătate sau
asistența prивitoare la costuri. Aveți dreptul de a obține gratuit aceste
informații și ajutor în limba dumneavoastră. Sunăți la 800-722-1471
(TTY: 800-842-5357).

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это
уведомление может содержать важную информацию о вашем
заявлении или страховом покрытии через Premera Blue Cross. В
настоящем уведомлении могут быть ключевые даты. Вам,
возможно, потребуется принять меры в определенные предельные
сроки для сохранения страхового покрытия или помощи с расходами.
У вас есть право на бесплатное получение этой информации
и помощь на вашем языке. Звоните по телефону 800-722-1471
(TTY: 800-842-5357).

Español (Spanish): Este Aviso contiene información importante. Es posible que este aviso
contenga información importante acerca de su solicitud o cobertura a
través de Premera Blue Cross. Es posible que haya fechas clave en este
aviso. Es posible que deba tomar alguna medida antes de determinadas
fechas para mantener su cobertura médica o ayuda con los costos. Usted
tiene derecho a recibir esta información y ayuda en su idioma sin costo

Тагальский (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang
paunawa na ito ay maring naglalaman ng mahalagang impormasyon tungkol
sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross.
Maaaring mga mahalagang petsa dito sa paunawa. Maaring mangailangahan ka na magagawa ng habang sa ibang mga ibang impormasyon
panahon upang mapanatili ang iyong pagsakop sa kalusugan o tungol
walang gastos. May karapatan ka na makausap ka ng galing impormasyon
at tungol sa iyong wika ng walang gastos. Tumawag sa 800-722-1471
(TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญเกี่ยวกับการขอรับสิทธิ์ในการส่งเสริม
สุขภาพของคุณผ่าน Premera Blue Cross และข้อมูลในการมีส่วนร่วมในการ คุณควรจะ
ดูดเอาข้อมูลในการกำหนดสถานะที่เหมาะสมและคุณสามารถขอรับการส่งเสริมสุขภาพที่มี
ใช้ประโยชน์ คุณมีสิทธิ์ที่จะได้รับข้อมูลและข้อมูลส่วนตัวในการส่งเสริมสุขภาพโดยไม่มีค่าใช้จ่าย โปรด
โทร 800-722-1471 (TTY: 800-842-5357).

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо
страховального покриття через Premera Blue Cross. Зверніть увагу на
ключові дати, які можуть бути вказані у цьому повідомленні. Існує
імовірність того, що Вам треба буде здійснити певні кроки у конкретні
кінцеві строки для того, щоб зберегти Ваше медичне страхування або
отримати фінансову допомогу. У Вас є право на отримання цієї
інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніть
за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):
Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông
tin quan trọng về đơn xin tham gia hoặc hỗ trợ bảo hiểm của quý vị qua
chương trình Premera Blue Cross. Xin xem ngay kreent trong thông báo
này. Quý vị có thể phải thực hiện thêm thông báo đúng trong thời hạn
dể duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý
vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình