



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 08/30/16
LAST REVIEW DATE: 07/31/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING AIDS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING AIDS (cont.)

Description:

Implantable Bone Anchored Hearing Aid (BAHA):

The BAHA implant system combines a vibrational transducer coupled directly to the skull by way of a percutaneous abutment that permanently protrudes through the skin from a small titanium implant anchored in the temporal bone. The system is based on the process of “osseointegration” through which living tissue integrates with titanium in the implant over a period of three to six months, allowing amplified and processed sound to be conducted by way of the skull bone directly to the cochlea. The lack of intervening skin allows the transmission of vibrations at a lower energy level than is required for external bone-conduction hearing aids. Also referred to as implantable bone conduction hearing aid. BAHA® sound processors for use with the BAHA auditory osseointegrated implant system include BAHA Cordelle II, BAHA Divino®, BAHA Intenso™ (digital signal processing), BAHA BP 100, BAHA 4 (upgraded from the BP100) and BAHA 5. The OBC Bone Anchored Hearing Aid System was also cleared by FDA. The Ponto™ Pro Processor can be used with the OBC Bone Anchored Hearing System or the BAHA implant.

Partially Implantable Magnetic Bone Conduction Hearing System:

Partially implantable magnetic bone conduction hearing systems have been used as an alternative to bone conduction hearing systems connected 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 for this device contains magnets that adhere externally to magnets implanted in shallow bone beds with the bone conduction hearing implant. Since the processor adheres magnetically to the implant, there is no need for a percutaneous abutment. To facilitate better transmission of acoustics between magnets, skin thickness may be reduced to 4-5 mm over the implant when it is surgically placed. Partially implantable magnetic bone conduction devices that have received FDA clearance include Otomag Bone Conduction system and Cochlear BAHA Attract. The BoneBridge™ is another partially implantable bone conduction implant that is cleared for marketing in Europe but has not received FDA approval for use in the U.S.

Definitions:

Types of Hearing Loss:

Conductive Hearing Loss:

Occurs when there is a mechanical problem in the external or middle ear and the auditory nerve remains intact. Conductive hearing loss can often be medically or surgically corrected.

Sensorineural Hearing Loss:

Occurs when there is damage to the inner ear (cochlea) or to the auditory nerve. This type of hearing loss usually cannot be medically or surgically corrected.

Mixed Hearing Loss:

A combination of conductive and sensorineural hearing loss. Damage exists in the external or middle ear and also in the inner ear or auditory nerve.



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 08/30/16
LAST REVIEW DATE: 07/31/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING AIDS (cont.)

Definitions: (cont.)

Degrees of Hearing Loss:

Mild Hearing Loss:

Pure-tone average (PTA) detection threshold 20 to 40 dB

Moderate Hearing Loss:

PTA detection threshold 40 to 60 dB

Severe Hearing Loss:

PTA detection threshold 60 to 80 dB

Profound Hearing Loss:

PTA detection threshold equal to or greater than 80 dB

Auditory Rehabilitation:

Hearing rehabilitation assessment and intervention for children and adults. Previously referred to as aural rehabilitation.

Evaluation of Auditory Rehabilitation Status:

Fundamental auditory and listening instruction for children who were not able to hear before receiving a cochlear implant, for adults with hearing loss who did not wear hearing aids and for children and adults who lost hearing and regained auditory function either with hearing aids or cochlear implants.

Auditory Rehabilitation Pre-lingual Hearing Loss:

Services performed for individuals who have no prior experience with hearing and are learning to hear through the use of hearing aids or cochlear implants.

Auditory Rehabilitation Post-lingual Hearing Loss:

Rehabilitation of adults who received a cochlear implant after a long period of time without functional hearing to assist in achieving speech understanding and identification of sounds.



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 08/30/16
LAST REVIEW DATE: 07/31/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING AIDS (cont.)

Criteria:

For cochlear implant, see BCBSAZ Medical Coverage Guideline #O724, "*Cochlear Implant*".

For conventional and digital hearing aids, non-implanted bone conduction hearing aids and non-implanted Bone Anchored Hearing Aids (BAHA®), see BCBSAZ Medical Coverage Guideline #O726, "*Conventional and Digital Hearing Aids*".

For semi-implantable and fully-implantable middle ear hearing aids, see BCBSAZ Medical Coverage Guideline #O725, "*Semi-Implantable and Fully Implantable Middle Ear Hearing Aids*".

COVERAGE FOR IMPLANTABLE BONE-CONDUCTION (BONE-ANCHORED) HEARING AIDS IS DEPENDENT UPON BENEFIT PLAN LANGUAGE. REFER TO MEMBER'S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS.

Unilateral Fully or Partially Implantable Bone-Conduction (Bone-Anchored) Hearing Aid:

- If benefit coverage for hearing aid is available, unilateral, fully or partially, implantable bone-conduction (bone-anchored) hearing aid and associated auditory rehabilitation is considered **medically necessary** with documentation of **ALL** of the following:
1. 5 years of age and older
 2. **ONE** of the following diagnoses:
 - Unilateral sensorineural deafness with normal hearing in the other ear (single sided deafness)
 - Unilateral conductive or mixed hearing loss
 3. Inability to restore hearing using a conventional hearing aid as the result of **ONE** of the following:
 - Chronic external otitis or otitis media
 - Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear
 - Dermatitis of the external canal
 - Narrowing of the ear canal to such a degree as to prevent introduction of a standard hearing aid
 - Tumors of the external canal and/or tympanic cavity



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 08/30/16
LAST REVIEW DATE: 07/31/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING AIDS (cont.)

Criteria: (cont.)

Unilateral Fully or Partially Implantable Bone-Conduction (Bone-Anchored) Hearing Aid: (cont.)

- **If benefit coverage for hearing aid is available, unilateral, fully or partially, implantable bone-conduction (bone-anchored) hearing aid and associated auditory rehabilitation is considered *medically necessary* with documentation of **ALL** of the following:** (cont.)
 4. Pure tone average bone conduction threshold of **ONE** of the following:
 - Greater than or equal to 45dB measured at 0.5, 1, 2 and 3 kHz for the OBC and BP100 devices
 - Greater than or equal to 55 dB measured at 0.5, 1, 2 and 3 kHz for the Intenso device
 - Greater than or equal to 65 dB measured at 0.5, 1, 2 and 3 kHz for the Cordelle II device
 5. Pure tone average air conduction threshold of the normal ear better than 20 dB measured at 0.5, 1, 2 and 3 kHz
- **If benefit coverage for hearing aid is available, replacement or upgrade of a unilateral, fully or partially, implantable bone-conduction (bone-anchored) hearing aid and/or its external components to a next generation device is considered *medically necessary* with documentation of **ANY** of the following:**
 1. The currently used component is no longer functional and cannot be repaired
 2. The currently used component is inadequate to the point of interfering with age-appropriate activities of daily living
- **If benefit coverage for hearing aid is available, replacement or upgrade of a functioning unilateral, fully or partially, implantable bone-conduction (bone-anchored) hearing aid and/or its external components to a next generation device to achieve aesthetic improvement, such as smaller profile components or a switch from a body-worn, external sound processor to a behind-the-ear model, is considered *not medically necessary*.**
- **Unilateral, fully or partially, implantable bone-conduction (bone-anchored) hearing aid for all other indications not previously listed or if above criteria not met is considered *not medically necessary*.**

IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING AIDS (cont.)

Criteria: (cont.)

Bilateral Fully or Partially Implantable Bone-Conduction (Bone-Anchored) Hearing Aid:

- **If benefit coverage for hearing aid is available, bilateral, fully or partially, implantable bone-conduction (bone-anchored) hearing aid and associated auditory rehabilitation is considered *medically necessary* with documentation of **ALL** of the following:**
 1. 5 years of age and older
 2. Pure tone average bone conduction threshold of **ONE** of the following:
 - Greater than or equal to 45dB measured at 0.5, 1, 2 and 3 kHz for the OBC and BP100 devices
 - Greater than or equal to 55 dB measured at 0.5, 1, 2 and 3 kHz for the Intenso device
 - Greater than or equal to 65 dB measured at 0.5, 1, 2 and 3 kHz for the Cordele II device
 3. Bilateral symmetric conductive and/or mixed hearing loss as defined by **ONE** of the following:
 - 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 for devices including but not limited to BAHAs BP 100, BAHAs Intenso and BAHAs Cordelle II, or less than 15 dB at individual frequencies
 - A difference between left and right side bone conduction threshold of less than 10 dB on average measured at 0.5, 1, 2 and 4 kHz for devices including but not limited to OBC BAHAs and Ponto Pro Bone Conduction Hearing System, or less than 15 dB at individual frequencies
 4. Inability to restore hearing using a conventional hearing aid as the result of **ONE** of the following:
 - Chronic external otitis or otitis media
 - Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear
 - Dermatitis of the external canal
 - Narrowing of the ear canal to such a degree as to prevent introduction of a standard hearing aid
 - Tumors of the external canal and/or tympanic cavity
- Fully or partially implantable bone-conduction (bone-anchored) hearing aid for an individual with bilateral sensorineural hearing loss is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 08/30/16
LAST REVIEW DATE: 07/31/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING AIDS (cont.)

Criteria: (cont.)

Bilateral Fully or Partially Implantable Bone-Conduction (Bone-Anchored) Hearing Aid (cont.)

- **If benefit coverage for hearing aid is available**, replacement or upgrade of a **bilateral**, fully or partially, implantable bone-conduction (bone-anchored) **hearing aid** and/or its external components to a next generation device is considered **medically necessary** with documentation of **ANY** of the following:
 1. The currently used component is no longer functional and cannot be repaired
 2. The currently used component is inadequate to the point of interfering with age-appropriate activities of daily living
- **If benefit coverage for hearing aid is available**, replacement or upgrade of a functioning **bilateral**, fully or partially, implantable bone-conduction (bone-anchored) hearing aid and/or its external components to a next generation device to achieve aesthetic improvement, such as smaller profile components or a switch from a body-worn, external sound processor to a behind-the-ear model, is considered **not medically necessary**.
- **Bilateral**, fully or partially, implantable bone-conduction (bone-anchored) hearing aid for all other indications not previously listed or if above criteria not met is considered **not medically necessary**.

Resources:

Literature reviewed 07/31/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 04/16/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.03 BCBS Association Medical Policy Reference Manual. Implantable Bone-Conduction and Bone-Anchored Hearing Aids. Re-issue date 02/08/2018, issue date 12/01/1995.



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 08/30/16
LAST REVIEW DATE: 07/31/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING AIDS (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'ánii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 08/30/16
LAST REVIEW DATE: 07/31/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING AIDS (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalín, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 [تماس حاصل نمایید].

Assyrian:

Blue Cross Blue Shield of Arizona , hese dawa dawa , anan usozanop izozanop , anan usozanop izozanop . 877-475-4799 .

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือคนที่คุณกำลังช่วยเหลือถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณจะได้รับความช่วยเหลือและข้อมูลในภาษา ของคุณได้โดยไม่มีค่าใช้จ่าย ติดต่อคุณถาม โทร 877-475-4799