SEMI-IMPLANTABLE AND FULLY IMPLANTABLE MIDDLE EAR 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.

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Semi-Implantable and Fully Implantable Middle Ear Hearing Aids
(cont.)

**Description:**
A hearing aid amplifies sound and requires the presence of hair cells for effectiveness.

**Semi-Implantable Middle Ear Hearing Aid:**
Depending upon the type of device, a processor is implanted either subcutaneously behind the affected ear or inside the outer ear. An electromagnetic implant is surgically attached to the ossicles in the middle ear. The processor converts sound into electromagnetic waves and transmits them causing the implant and the ossicles to vibrate, mimicking the natural hearing process. Devices include the Vibrant® Soundbridge™ and the Soundtec®. As of April 2011, it has been reported that the Soundtec has been discontinued by the manufacturer.

**Fully Implantable Middle Ear Hearing Aid:**
A piezoelectric transducer (the sensor) is implanted at the head of the incus and converts mechanical vibrations detected from the tympanic membrane to electrical signals delivered to the stapes by another piezoelectric transducer (the driver). Devices include, but are not limited to, the Esteem® Implantable Hearing System.

**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.

**Degrees of Hearing Loss:**

**Mild Hearing Loss:**
Pure-tone average (PTA) detection threshold 20 to 40 dB

**Moderate Hearing Loss:**
P TA detection threshold 40 to 60 dB

**Severe Hearing Loss:**
P TA detection threshold 60 to 80 dB
SEMI-IMPLANTABLE AND FULLY IMPLANTABLE MIDDLE EAR HEARING AIDS  
(cont.)

Definitions: (cont.)

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.

Criteria:

For cochlear implants, 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 implantable bone-conduction and bone-anchored hearing aids, see BCBSAZ Medical Coverage Guideline #O723, “Implantable Bone-Conduction and Bone-Anchored Hearing Aids”.

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SEMI-IMPLANTABLE AND FULLY IMPLANTABLE MIDDLE EAR HEARING AIDS
(cont.)

Criteria: (cont.)

Semi-Implantable Middle Ear Hearing Aid:

COVERAGE FOR SEMI-IMPLANTABLE MIDDLE EAR HEARING AID IS DEPENDENT UPON BENEFIT PLAN LANGUAGE. REFER TO MEMBER’S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS.

If benefit coverage for hearing aid is available, semi-implantable middle ear hearing aid and associated auditory rehabilitation is considered medically necessary with documentation of ALL of the following:

1. 18 years of age and older
2. Moderate to severe sensorineural hearing loss
3. Inability to restore hearing using a conventional hearing aid as the result of ONE of the following:
   - Chronic dermatitis of the external canal
   - Chronic external otitis or otitis media
   - Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear
   - 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
4. Pure tone average bone conduction threshold of the affected ear is > 45dB HL
5. Speech discrimination score better than 60%

If benefit coverage for hearing aid is available, replacement or upgrade of a semi-implantable middle ear 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 semi-implantable middle ear 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.
SEMI-IMPLANTABLE AND FULLY IMPLANTABLE MIDDLE EAR HEARING AIDS
(cont.)

Criteria: (cont.)

- Semi-implantable middle ear hearing aid for all other indications not previously listed is considered not medically necessary.

Fully Implantable Middle Ear Hearing Aid:

Coverage for fully implantable ear hearing aid is dependent upon benefit plan language. Refer to member's specific benefit plan booklet to verify benefits.

- If benefit coverage for hearing aid is available, fully implantable hearing aid 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.

Resources:

Literature reviewed 03/20/18. 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.


FDA Premarket Approval Database for Maxum™ System:

- FDA-approved indication: For use in adults, 18 years of age or older, who have a moderate to severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid.
SEMI-IMPLANTABLE AND FULLY IMPLANTABLE MIDDLE EAR HEARING AIDS
(cont.)

Resources: (cont.)

FDA Premarket Approval Database for Vibrant Soundbridge™ System:

- FDA-approved indication: For use in adults, 18 years of age or older, who have a moderate to severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid.

FDA Premarket Approval Database for Esteem Totally Implantable Hearing System:

- FDA-approved indication: To alleviate hearing loss in patients by replicating the ossicular chain and providing additional gain. The esteem is indicated for patients with hearing loss that meet the following criteria: 1) 18 years of age or older; 2) stable bilateral sensorineural hearing loss; 3) moderate to severe sensorineural hearing loss defined by pure tone average (ptA); 4) unaided speech discrimination test score greater than or equal to 40%; 5) normally functioning eustachian tube; 6) normal middle ear anatomy; 7) normal tympanic membrane; 8) adequate space for esteem implant determined via a high resolution ct scan; and 9) minimum 30 days of experience with appropriately fit hearing aids.
Semi-Implantable and Fully Implantable Middle Ear 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, 20 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 kweé atah nilnii gíí Blue Cross Blue Shield of Arizona haadí yít’éego bíná’dííldíígo áli doodago Hááda bii já aniyeedíí gi t’aadood lée’é víná’dííldíígo beehaz’áánii hóló díí t’áa hazaad’éhéí hááka a’doowolgo bee haz’á doo bááh ilíílníí. Ata’ halne’ígíígi koj’é bich’é’ hodiilini 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, hoặc 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 thợ dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعد أسألة بخصوص Blue Cross Blue Shield of Arizona، فلتدى الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أي تكلفة للتحدث مع مت地狱 المصلب 877-475-4799.
Semi-Implantable and Fully Implantable Middle Ear 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 makuusap ang isang tagasalin, tumawag sa 877-475-4799.

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

آگه شما یا کسی که شما به او کمک میکنید سوالاتی در مورد اطلاعاتی به زبان خود را به مدرک انگلیسی که در وابسته های 877-475-4799 ثبت شده‌اند می‌توانید بپرسید.

Assyrian:


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: หากคุณหรือคนใกล้ชิดของคุณไม่ได้รับการสนับสนุนจาก Blue Cross Blue Shield of Arizona คุณสามารถจะติดต่อเจ้าหน้าที่สายด่วนของคุณได้โดยไม่ต้องเสียค่าโทรศัพท์ โทรหมายเลข 877-475-4799