Implantable Bone-Conduction and Bone-Anchored Hearing Aids

Policy # 00004
Original Effective Date: 06/24/2002
Current Effective Date: 08/12/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider an implantable bone-conduction (bone-anchored) hearing aid as an alternative to an air-conduction contralateral routing of signal hearing aid in individuals five 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 decibel (dB) measured at 0.5, 1, 2, and 3 kilohertz (kHz) to be **eligible for coverage.****

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of unilateral or bilateral fully or partially implantable bone-conduction (bone-anchored) hearing aid(s) as an alternative to air-conduction hearing aid in individuals with a conductive or mixed hearing loss to be **eligible for coverage.****

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Patient Selection Criteria

Coverage eligibility for the use of unilateral or bilateral fully or partially implantable bone-conduction (bone-anchored) hearing aids as an alternative to an air-conduction hearing aid in individuals 5 years of age and older with a conductive or mixed hearing loss will be considered when at least 1 of the following criteria are met:

- Congenital or surgically induced malformations (e.g., 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**

Meet the following audiologic criteria:

- For percutaneous devices, A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kilohertz (kHz) of better than or equal to 45 decibel (dB) (OBC and BP100 devices), 55 decibel (dB) (Intenso device) or 65 decibel (dB) (Cordele II device).
- For transcutaneous devices, A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kilohertz (kHz) of better than or equal to 45 decibel (dB) (BAHA Attract and Sophono (passive) devices) or 55 decibel (dB) (Cochlear Osia and Med-El Bonebridge (active) devices).
- For bilateral implantation, individuals should meet the above audiologic 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 decibel (dB) on average measured at 0.5, 1, 2 and 3 kilohertz (kHz), (4 kHz for OBC and Ponto Pro) or less than 15 decibel (dB) at individual frequencies.

Based on review of available data, the Company may consider FDA-approved non-osseointegrated hearing device including a headband or other means of external attachment (**e.g.,** BAHA Soft Band, BAHA SoundArc, or MED-EL Adhere) when above selection criteria for bone-anchored hearing aids (osseointegrated) are met, to be **eligible for coverage.****

***Note**: This requirement is applicable only to adults age 18 or older with adult hearing aid benefits. Hearing aid benefit limitations apply to non-osseointegrated hearing devices. Non-osseoinegrated hearing devices are not covered under plans that exclude coverage of hearing aids.*

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in individuals with bilateral sensorineural hearing loss, to be **investigational.***

Based on review of available data, the Company considers non-osseointegrated hearing devices when patient selection criteria are not met to be **investigational.***

Based on review of available data, the Company considers implantable bone conduction hearing aids when patient selection criteria are not met to be **investigational.***

Policy Guidelines

In individuals 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, individuals (or caregivers) must be able to perform proper hygiene to prevent infection and ensure the stability of the implants and percutaneous abutments.

Background/Overview

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 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 to 8 kHz.

Sound amplification using an air-conduction (AC) hearing aid can provide benefit to individuals 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 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 or 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.

Partially implantable magnetic bone-conduction hearing systems also referred to as transcutaneous bone-anchored systems, are an alternative to 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 may be reduced to 4 to 5 mm over the implant when it is surgically placed.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several implantable bone-conduction hearing systems have been approved by the U.S. FDA for marketing through the 510(k) process (Table 1).

Table 1. Implantable Bone-Conduction Hearing Systems Approved by the U.S Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.
Baha 6 System	Cochlear Americas	Sept 2021	K212136
BA310 Abutment, BIA310 Implant/Abutment		Dec 2018	K182116
Baha 5 Power Sound Processor		May 2016	K161123
Baha 5 Super Power Sound Processor		Mar 2016	K153245
Baha®‡ 5 Sound Processor		Mar 2015	K142907
Baha®‡ Attract System		Nov 2013	K131240
Baha®‡ Cordelle II		Jul 2015 Apr 2008	K150751 K080363
Baha Divino®‡		Aug 2004	K042017
Baha Intenso®‡ (digital signal processing)		Aug 2008	K081606
Baha®‡ 4 (upgraded from the BP100)		Sep 2013	K132278
Cochlear™ Osia™2 System		Dec 2019	K191921
OBC Bone-Anchored Hearing Aid System	Oticon Medical	Nov 2011	K112053
Ponto Bone-Anchored Hearing System	Oticon Medical	Sep 2012	K121228
Ponto 5 SuperPower	Oticon Medical	Dec 2021	K213733

Ponto 4		May 2019	K190540
Ponto 3, Ponto 3 Power and Ponto 3 SuperPower		Sep 2016	K161671

The FDA cleared the majority of these systems for use in children age 5 years and older and adults for the following indications:

- Individuals who have conductive or mixed hearing loss and can still benefit from sound amplification;
- Individuals with bilaterally symmetric conductive or mixed hearing loss, may be implanted bilaterally;
- Individuals with sensorineural deafness in 1 ear and normal hearing in the other (ie, single-sided deafness);
- Individuals 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. Because this application has no implanted components, it is not addressed in this evidence review.

In 2009, the FDA cleared the Cochlear Baha BP100 sound processor that is intended for use with the Baha auditory osseointegrated implant (for children aged 5 and older, or adults), or with the Baha Headband or Baha Softband (no age limitations) for the following patients and indications:

- Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB HL.
- Bilateral fitting of the BP100 is intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies.

- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e., single-sided deafness or "SSD"). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to .20 dB HL.
- Baha for SSD is also indicated for any patient who is indicated for an air conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

Refer to the following website for more information:
http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090720.pdf.

The BAHA SoundArc received FDA clearance on June 7, 2017. The BAHA SoundArc is intended for patients who cannot or choose not to have an implant for the following indications for use:

- Patients of any age who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3kHz) should be better than or equal to 45 dB HL for use with the BP100, Baha 4 and Baha 5 sound processors, 55 dB HL for use with the BP110 Power and Baha 5 Power sound processors, and better than or equal to 65 dB HL for use with the Cordelle II and Baha 5 SuperPower Sound Processors.
- Bilateral fitting is intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conductive thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1,2, and 3 kHz), or less than a 15dB difference at individual frequencies.
- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e. Single-sided deafness: SSDTM). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL.
- Baha for SSD is also indicated for any patient who is indicated for an air conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

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Refer to the following website for more information:
https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171088.pdf.

The Bonebridge (MED-EL), a transcutaneous bone-conduction hearing device was cleared by the FDA via the de novo regulatory pathway on July 20, 2018. The de novo process provides a pathway to classify low- to moderate-risk devices for which general controls or general and special controls provide reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. The Bonebridge bone conduction hearing implant system is intended for the following patients and indications:

- Patients 12 years of age or older.
- Patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5,1, 2, and 3 kHz) should be better than or equal to 45 dB HL.
- Bilateral fitting of the Bonebridge is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies.
- Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single-sided deafness [SSD]). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- The Bonebridge for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.
- Before receiving the device, it is recommended that an individual have experience with appropriately fit air conduction or bone conduction hearing aids.

The FDA subsequently granted 510(k) marketing clearance (K183373) for the Bonebridge in March 2019. Refer to the following websites for more information:

- https://www.accessdata.fda.gov/cdrh_docs/pdf17/DEN170009.pdf
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K183373

The most recently cleared Osia™‡ 2 system may be used by adults and children 12 years of age and older with conductive hearing loss, mixed hearing loss, and single-sided sensorineural deafness.

The FDA also cleared 3 partially implantable magnetic bone-conduction devices for marketing through the 510(k) process (Table 2).

Table 2. Partially Implantable Magnetic Bone-Conduction Devices Approved by the U.S Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.
Bonebridge	MED-EL	Mar 2019	K183373
Otomag®‡ Bone-Conduction Hearing System	Medtronic (Formerly Sophono)	Nov 2013	K132189
Cochlear Baha®‡ 4 Sound Processor	Cochlear Americas	Oct 2012	K121317

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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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 individuals 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 individuals with conductive or mixed hearing loss or for individuals with unilateral single-sided sensorineural hearing loss.

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 an 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 individuals, 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 individuals and, therefore, does not provide definitive evidence. Quality RCTs on BAHA for unilateral sensorineural hearing loss are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

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.

2016 Clinical Input

In response to requests, input was received from 2 specialty societies and 3 academic medical centers (1 of which provided 4 responses and 1 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 2 are not necessary.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Otolaryngology Head and Neck Surgery

In 2021, the American Academy of Otolaryngology Head and Neck Surgery updated its position statement on the use of implantable hearing devices. It states that the Academy “considers bone conduction hearing devices (BCHD) as appropriate, and in some cases preferred, for the treatment of conductive and mixed hearing loss. BCHD may also be indicated in select individuals with single-sided deafness. BCHD include semi-implantable bone conduction devices utilizing either a percutaneous or transcutaneous attachment, as well as bone conduction oral appliances and scalp-

worn devices. The recommendation for BCHD should be determined by a qualified otolaryngology-head and neck surgeon. These devices are approved by the Food and Drug Administration (FDA) for these indications, and their use should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the FDA in the United States and the respective regulatory agencies in countries other than the United States."

U.S. Preventive Services Task Force Recommendations
Not applicable.

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. 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."

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	***Trial Name***	***Planned Enrollment***	***Completion Date***
Ongoing			
NCT05615649[a]	Expanded Indications in the Pediatric BONEBRIDGE Population	36	Jun 2025 (not yet recruiting)

NCT03533686	Comparative Study of Non-invasive Adhear Bone Conduction System to Traditional Bone Conduction Hearing Devices	90	Mar 2023 (Recruiting)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. Heath E, Dawoud MM, Stavrakas M, et al. The outcomes of bilateral bone conduction hearing devices (BCHD) implantation in the treatment of hearing loss: A systematic review. Cochlear Implants Int. Mar 2022; 23(2): 95-108. PMID 34852723
2. Janssen RM, Hong P, Chadha NK. Bilateral bone-anchored hearing aids for bilateral permanent conductive hearing loss: a systematic review. Otolaryngol Head Neck Surg. Sep 2012; 147(3): 412-22. PMID 22714424
3. Bosman AJ, Snik AF, van der Pouw CT, et al. Audiometric evaluation of bilaterally fitted bone-anchored hearing aids. Audiology. 2001; 40(3): 158-67. PMID 11465298
4. Priwin C, Stenfelt S, Granström G, et al. Bilateral bone-anchored hearing aids (BAHAs): an audiometric evaluation. Laryngoscope. Jan 2004; 114(1): 77-84. PMID 14709999
5. Snik AF, Mylanus EA, Proops DW, et al. Consensus statements on the BAHA system: where do we stand at present?. Ann Otol Rhinol Laryngol Suppl. Dec 2005; 195: 2-12. PMID 16619473
6. Dun CA, de Wolf MJ, Mylanus EA, et al. Bilateral bone-anchored hearing aid application in children: the Nijmegen experience from 1996 to 2008. Otol Neurotol. Jun 2010; 31(4): 615-23. PMID 20393374
7. Ho EC, Monksfield P, Egan E, et al. Bilateral Bone-anchored Hearing Aid: impact on quality of life measured with the Glasgow Benefit Inventory. Otol Neurotol. Oct 2009; 30(7): 891-6. PMID 19692937
8. Briggs R, Van Hasselt A, Luntz M, et al. Clinical performance of a new magnetic bone conduction hearing implant system: results from a prospective, multicenter, clinical investigation. Otol Neurotol. Jun 2015; 36(5): 834-41. PMID 25634465
9. Denoyelle F, Coudert C, Thierry B, et al. Hearing rehabilitation with the closed skin bone-anchored implant Sophono Alpha1: results of a prospective study in 15 children with ear atresia. Int J Pediatr Otorhinolaryngol. Mar 2015; 79(3): 382-7. PMID 25617189

10. Gawęcki W, Gibasiewicz R, Marszał J, et al. The evaluation of a surgery and the short-term benefits of a new active bone conduction hearing implant - the Osia®. Braz J Otorhinolaryngol. 2022; 88(3): 289-295. PMID 32713797
11. Hol MK, Nelissen RC, Agterberg MJ, et al. Comparison between a new implantable transcutaneous bone conductor and percutaneous bone-conduction hearing implant. Otol Neurotol. Aug 2013; 34(6): 1071-5. PMID 23598702
12. Nelissen RC, Agterberg MJ, Hol MK, et al. Three-year experience with the Sophono in children with congenital conductive unilateral hearing loss: tolerability, audiometry, and sound localization compared to a bone-anchored hearing aid. Eur Arch Otorhinolaryngol. Oct 2016; 273(10): 3149-56. PMID 26924741
13. Iseri M, Orhan KS, Tuncer U, et al. Transcutaneous Bone-anchored Hearing Aids Versus Percutaneous Ones: Multicenter Comparative Clinical Study. Otol Neurotol. Jun 2015; 36(5): 849-53. PMID 25730451
14. Gerdes T, Salcher RB, Schwab B, et al. Comparison of Audiological Results Between a Transcutaneous and a Percutaneous Bone Conduction Instrument in Conductive Hearing Loss. Otol Neurotol. Jul 2016; 37(6): 685-91. PMID 27093021
15. Kim Y, Choe G, Oh H, et al. A comparative study of audiological outcomes and compliance between the Osia system and other bone conduction hearing implants. Eur Arch Otorhinolaryngol. Nov 01 2022. PMID 36318324
16. Dimitriadis PA, Farr MR, Allam A, et al. Three year experience with the cochlear BAHA attract implant: a systematic review of the literature. BMC Ear Nose Throat Disord. 2016; 16: 12. PMID 27733813
17. Reddy-Kolanu R, Gan R, Marshall AH. A case series of a magnetic bone conduction hearing implant. Ann R Coll Surg Engl. Nov 2016; 98(8): 552-553. PMID 27490984
18. Siegert R. Partially implantable bone conduction hearing aids without a percutaneous abutment (Otomag): technique and preliminary clinical results. Adv Otorhinolaryngol. 2011; 71: 41-46. PMID 21389703
19. Powell HR, Rolfe AM, Birman CS. A Comparative Study of Audiologic Outcomes for Two Transcutaneous Bone-Anchored Hearing Devices. Otol Neurotol. Sep 2015; 36(9): 1525-31. PMID 26375976
20. O'Niel MB, Runge CL, Friedland DR, et al. Patient Outcomes in Magnet-Based Implantable Auditory Assist Devices. JAMA Otolaryngol Head Neck Surg. Jun 2014; 140(6): 513-20. PMID 24763485

21. Centric A, Chennupati SK. Abutment-free bone-anchored hearing devices in children: initial results and experience. Int J Pediatr Otorhinolaryngol. May 2014; 78(5): 875-8. PMID 24612554
22. Baker S, Centric A, Chennupati SK. Innovation in abutment-free bone-anchored hearing devices in children: Updated results and experience. Int J Pediatr Otorhinolaryngol. Oct 2015; 79(10): 1667-72. PMID 26279245
23. Marsella P, Scorpecci A, Vallarino MV, et al. Sophono in Pediatric Patients: The Experience of an Italian Tertiary Care Center. Otolaryngol Head Neck Surg. Aug 2014; 151(2): 328-32. PMID 24714216
24. Magliulo G, Turchetta R, Iannella G, et al. Sophono Alpha System and subtotal petrosectomy with external auditory canal blind sac closure. Eur Arch Otorhinolaryngol. Sep 2015; 272(9): 2183-90. PMID 24908070
25. Carnevale C, Morales-Olavarría C, Til-Pérez G, et al. Bonebridge® bone conduction implant. Hearing outcomes and quality of life in patients with conductive/mixed hearing loss. Eur Arch Otorhinolaryngol. Sep 05 2022. PMID 36063211
26. Cywka KB, Skarzynski PH, Krol B, et al. Evaluation of the Bonebridge BCI 602 active bone conductive implant in adults: efficacy and stability of audiological, surgical, and functional outcomes. Eur Arch Otorhinolaryngol. Jul 2022; 279(7): 3525-3534. PMID 35182185
27. Huber AM, Strauchmann B, Caversaccio MD, et al. Multicenter Results With an Active Transcutaneous Bone Conduction Implant in Patients With Single-sided Deafness. Otol Neurotol. Feb 01 2022; 43(2): 227-235. PMID 34816809
28. Hundertpfund J, Meyer JE, Ovari A. Long-term audiological benefit with an active transcutaneous bone-conduction device: a retrospective cohort analysis. Eur Arch Otorhinolaryngol. Jul 2022; 279(7): 3309-3326. PMID 34424382
29. Seiwerth I, Fröhlich L, Schilde S, et al. Clinical and functional results after implantation of the bonebridge, a semi-implantable, active transcutaneous bone conduction device, in children and adults. Eur Arch Otorhinolaryngol. Jan 2022; 279(1): 101-113. PMID 33674927
30. Šikolová S, Urík M, Hošnová D, et al. Two Bonebridge bone conduction hearing implant generations: audiological benefit and quality of hearing in children. Eur Arch Otorhinolaryngol. Jul 2022; 279(7): 3387-3398. PMID 34495351
31. Bravo-Torres S, Der-Mussa C, Fuentes-López E. Active transcutaneous bone conduction implant: audiological results in paediatric patients with bilateral microtia associated with external auditory canal atresia. Int J Audiol. Jan 2018; 57(1): 53-60. PMID 28857620

32. Schmerber S, Deguine O, Marx M, et al. Safety and effectiveness of the Bonebridge transcutaneous active direct-drive bone-conduction hearing implant at 1-year device use. Eur Arch Otorhinolaryngol. Apr 2017; 274(4): 1835-1851. PMID 27475796
33. Rahne T, Seiwerth I, Götze G, et al. Functional results after Bonebridge implantation in adults and children with conductive and mixed hearing loss. Eur Arch Otorhinolaryngol. Nov 2015; 272(11): 3263-9. PMID 25425039
34. Laske RD, Röösli C, Pfiffner F, et al. Functional Results and Subjective Benefit of a Transcutaneous Bone Conduction Device in Patients With Single-Sided Deafness. Otol Neurotol. Aug 2015; 36(7): 1151-6. PMID 26111077
35. Riss D, Arnoldner C, Baumgartner WD, et al. Indication criteria and outcomes with the Bonebridge transcutaneous bone-conduction implant. Laryngoscope. Dec 2014; 124(12): 2802-6. PMID 25142577
36. Manrique M, Sanhueza I, Manrique R, et al. A new bone conduction implant: surgical technique and results. Otol Neurotol. Feb 2014; 35(2): 216-20. PMID 24448280
37. Ihler F, Volbers L, Blum J, et al. Preliminary functional results and quality of life after implantation of a new bone conduction hearing device in patients with conductive and mixed hearing loss. Otol Neurotol. Feb 2014; 35(2): 211-5. PMID 24448279
38. Desmet J, Wouters K, De Bodt M, et al. Long-term subjective benefit with a bone conduction implant sound processor in 44 patients with single-sided deafness. Otol Neurotol. Jul 2014; 35(6): 1017-25. PMID 24751733
39. Işeri M, Orhan KS, Kara A, et al. A new transcutaneous bone anchored hearing device - the Baha® Attract System: the first experience in Turkey. Kulak Burun Bogaz Ihtis Derg. 2014; 24(2): 59-64. PMID 24835899
40. Peters JP, Smit AL, Stegeman I, et al. Review: Bone conduction devices and contralateral routing of sound systems in single-sided deafness. Laryngoscope. Jan 2015; 125(1): 218-26. PMID 25124297
41. Baguley DM, Bird J, Humphriss RL, et al. The evidence base for the application of contralateral bone anchored hearing aids in acquired unilateral sensorineural hearing loss in adults. Clin Otolaryngol. Feb 2006; 31(1): 6-14. PMID 16441794
42. den Besten CA, Monksfield P, Bosman A, et al. Audiological and clinical outcomes of a transcutaneous bone conduction hearing implant: Six-month results from a multicentre study. Clin Otolaryngol. Mar 2019; 44(2): 144-157. PMID 30358920

43. Leterme G, Bernardeschi D, Bensemman A, et al. Contralateral routing of signal hearing aid versus transcutaneous bone conduction in single-sided deafness. Audiol Neurootol. 2015; 20(4): 251-60. PMID 26021779
44. Snapp HA, Holt FD, Liu X, et al. Comparison of Speech-in-Noise and Localization Benefits in Unilateral Hearing Loss Subjects Using Contralateral Routing of Signal Hearing Aids or Bone-Anchored Implants. Otol Neurotol. Jan 2017; 38(1): 11-18. PMID 27846038
45. Zeitler DM, Snapp HA, Telischi FF, et al. Bone-anchored implantation for single-sided deafness in patients with less than profound hearing loss. Otolaryngol Head Neck Surg. Jul 2012; 147(1): 105-11. PMID 22368043
46. Pai I, Kelleher C, Nunn T, et al. Outcome of bone-anchored hearing aids for single-sided deafness: a prospective study. Acta Otolaryngol. Jul 2012; 132(7): 751-5. PMID 22497318
47. Saroul N, Akkari M, Pavier Y, et al. Long-term benefit and sound localization in patients with single-sided deafness rehabilitated with an osseointegrated bone-conduction device. Otol Neurotol. Jan 2013; 34(1): 111-4. PMID 23202156
48. Lin LM, Bowditch S, Anderson MJ, et al. Amplification in the rehabilitation of unilateral deafness: speech in noise and directional hearing effects with bone-anchored hearing and contralateral routing of signal amplification. Otol Neurotol. Feb 2006; 27(2): 172-82. PMID 16436986
49. Kunst SJ, Leijendeckers JM, Mylanus EA, et al. Bone-anchored hearing aid system application for unilateral congenital conductive hearing impairment: audiometric results. Otol Neurotol. Jan 2008; 29(1): 2-7. PMID 18199951
50. Kunst SJ, Hol MK, Mylanus EA, et al. Subjective benefit after BAHA system application in patients with congenital unilateral conductive hearing impairment. Otol Neurotol. Apr 2008; 29(3): 353-58. PMID 18494142
51. Gluth MB, Eager KM, Eikelboom RH, et al. Long-term benefit perception, complications, and device malfunction rate of bone-anchored hearing aid implantation for profound unilateral sensorineural hearing loss. Otol Neurotol. Dec 2010; 31(9): 1427-34. PMID 20729779
52. Faber HT, Nelissen RC, Kramer SE, et al. Bone-anchored hearing implants in single-sided deafness patients: Long-term use and satisfaction by gender. Laryngoscope. Dec 2015; 125(12): 2790-5. PMID 26152833
53. Monini S, Musy I, Filippi C, et al. Bone conductive implants in single-sided deafness. Acta Otolaryngol. Apr 2015; 135(4): 381-8. PMID 25720582

54. AlFarraj A, AlIbrahim M, AlHajjaj H, et al. Transcutaneous Bone Conduction Implants in Patients With Single-Sided Deafness: Objective and Subjective Evaluation. Ear Nose Throat J. May 02 2022: 1455613221099996. PMID 35499947
55. Amonoo-Kuofi K, Kelly A, Neeff M, et al. Experience of bone-anchored hearing aid implantation in children younger than 5 years of age. Int J Pediatr Otorhinolaryngol. Apr 2015; 79(4): 474-80. PMID 25680294
56. Marsella P, Scorpecci A, Pacifico C, et al. Pediatric BAHA in Italy: the "Bambino Gesù" Children's Hospital's experience. Eur Arch Otorhinolaryngol. Feb 2012; 269(2): 467-74. PMID 21739094
57. Davids T, Gordon KA, Clutton D, et al. Bone-anchored hearing aids in infants and children younger than 5 years. Arch Otolaryngol Head Neck Surg. Jan 2007; 133(1): 51-5. PMID 17224524
58. McDermott AL, Williams J, Kuo MJ, et al. The role of bone anchored hearing aids in children with Down syndrome. Int J Pediatr Otorhinolaryngol. Jun 2008; 72(6): 751-7. PMID 18433885
59. Schwab B, Wimmer W, Severens JL, et al. Adverse events associated with bone-conduction and middle-ear implants: a systematic review. Eur Arch Otorhinolaryngol. Feb 2020; 277(2): 423-438. PMID 31749056
60. Verheij E, Bezdjian A, Grolman W, et al. A Systematic Review on Complications of Tissue Preservation Surgical Techniques in Percutaneous Bone Conduction Hearing Devices. Otol Neurotol. Aug 2016; 37(7): 829-37. PMID 27273402
61. Kiringoda R, Lustig LR. A meta-analysis of the complications associated with osseointegrated hearing aids. Otol Neurotol. Jul 2013; 34(5): 790-4. PMID 23739555
62. Dun CA, Faber HT, de Wolf MJ, et al. Assessment of more than 1,000 implanted percutaneous bone conduction devices: skin reactions and implant survival. Otol Neurotol. Feb 2012; 33(2): 192-8. PMID 22246385
63. Hobson JC, Roper AJ, Andrew R, et al. Complications of bone-anchored hearing aid implantation. J Laryngol Otol. Feb 2010; 124(2): 132-6. PMID 19968889
64. Wallberg E, Granström G, Tjellström A, et al. Implant survival rate in bone-anchored hearing aid users: long-term results. J Laryngol Otol. Nov 2011; 125(11): 1131-5. PMID 21774847
65. Kraai T, Brown C, Neeff M, et al. Complications of bone-anchored hearing aids in pediatric patients. Int J Pediatr Otorhinolaryngol. Jun 2011; 75(6): 749-53. PMID 21470698
66. Allis TJ, Owen BD, Chen B, et al. Longer length Baha™ abutments decrease wound complications and revision surgery. Laryngoscope. Apr 2014; 124(4): 989-92. PMID 24114744

67. Calvo Bodnia N, Foghsgaard S, Nue Møller M, et al. Long-term results of 185 consecutive osseointegrated hearing device implantations: a comparison among children, adults, and elderly. Otol Neurotol. Dec 2014; 35(10): e301-6. PMID 25122598
68. Rebol J. Soft tissue reactions in patients with bone anchored hearing aids. Ir J Med Sci. Jun 2015; 184(2): 487-91. PMID 24913737
69. Larsson A, Tjellström A, Stalfors J. Implant losses for the bone-anchored hearing devices are more frequent in some patients. Otol Neurotol. Feb 2015; 36(2): 336-40. PMID 24809279
70. den Besten CA, Nelissen RC, Peer PG, et al. A Retrospective Cohort Study on the Influence of Comorbidity on Soft Tissue Reactions, Revision Surgery, and Implant Loss in Bone-anchored Hearing Implants. Otol Neurotol. Jun 2015; 36(5): 812-8. PMID 25811351
71. Mohamad S, Khan I, Hey SY, et al. A systematic review on skin complications of bone-anchored hearing aids in relation to surgical techniques. Eur Arch Otorhinolaryngol. Mar 2016; 273(3): 559-65. PMID 25503356
72. Fontaine N, Hemar P, Schultz P, et al. BAHA implant: implantation technique and complications. Eur Ann Otorhinolaryngol Head Neck Dis. Feb 2014; 131(1): 69-74. PMID 23835074
73. Hultcrantz M, Lanis A. A five-year follow-up on the osseointegration of bone-anchored hearing device implantation without tissue reduction. Otol Neurotol. Sep 2014; 35(8): 1480-5. PMID 24770406
74. Nelissen RC, Stalfors J, de Wolf MJ, et al. Long-term stability, survival, and tolerability of a novel osseointegrated implant for bone conduction hearing: 3-year data from a multicenter, randomized, controlled, clinical investigation. Otol Neurotol. Sep 2014; 35(8): 1486-91. PMID 25080037
75. Singam S, Williams R, Saxby C, et al. Percutaneous bone-anchored hearing implant surgery without soft-tissue reduction: up to 42 months of follow-up. Otol Neurotol. Oct 2014; 35(9): 1596-600. PMID 25076228
76. Roplekar R, Lim A, Hussain SS. Has the use of the linear incision reduced skin complications in bone-anchored hearing aid implantation?. J Laryngol Otol. Jun 2016; 130(6): 541-4. PMID 27160014
77. American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Bone Conduction Hearing Devices. Position Statements 2016; https://www.entnet.org/resource/position-statement-bone-conduction-hearing-devices/.

78. Centers for Medicare & Medicaid Services. Medicare Policy Benefit Manual. Chapter 16 - General Exclusions from Coverage (Rev. 198). 2014; Rev. 189. http://www.cms.gov/manuals/Downloads/bp102c16.pdf.
79. Centers for Medicare & Medicaid Services. Fact sheets: CMS Updates Policies and Payment Rates for End- Stage Renal Disease Facilities for CY 2015 and Implementation of Competitive Bidding-Based Prices for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. 2014; https://www.cms.gov/newsroom/fact-sheets/cms-updates-policies-and-payment-rates-end-stage-renal-disease-facilities-cy-2015-and-implementation.

Policy History

Original Effective Date: 06/24/2002
Current Effective Date: 08/12/2024

06/11/2002	Medical Director review
06/20/2002	Medical Policy Committee review
06/24/2002	Managed Care Advisory Council approval. Format revision. No substance change to policy.
07/06/2004	Medical Director review
07/20/2004	Medical Policy Committee review. Format revision, Rationale/Source added to policy. No substance change to policy.
07/26/2004	Managed Care Advisory Council approval
06/07/2005	Medical Director review
06/21/2005	Medical Policy Committee review. Clinical criteria change. Coverage for single sided deafness and bilateral fittings added as investigational indication.
07/15/2005	Managed Care Advisory Council approval
06/13/2006	Format revisions. No changes to policy statement.
08/02/2006	Medical Director review
08/09/2006	Medical Policy Committee approval. Patient selection criteria updated to include age limitations.
10/10/2007	Medical Director review
10/17/2007	Medical Policy Committee approval. Policy statements updated and clarified related to eligibility for coverage for unilateral and bilateral sensorineural hearing loss. Policy statement added concerning investigational uses, including bilateral sensorineural hearing loss. Policy title changed to add “and Bone-Anchored”.

10/01/2008	Medical Director review
10/22/2008	Medical Policy Committee approval. No change to coverage eligibility.
10/01/2009	Medical Policy Committee approval
10/14/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
10/14/2010	Medical Policy Committee review
10/20/2010	Medical Policy Implementation Committee approval. The age requirement in the coverage language changed to be consistent with FDA-approved labeling from "patients over five years of age" to "patients five years of age and older". Coverage that stands alone without criteria placed under the subtitle "When Services Are Eligible for Coverage".
02/01/2011	Coding updated
10/06/2011	Medical Policy Committee review
10/19/2011	Medical Policy Implementation Committee approval. Audiologic criteria revised to read: 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 audiologic 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, or less than 15 dB at individual frequencies.
10/11/2012	Medical Policy Committee review
10/31/2012	Medical Policy Implementation Committee approval. Added investigational statement for partially implantable hearing systems.
02/04/2013	Coding updated
10/03/2013	Medical Policy Committee review
10/16/2013	Medical Policy Implementation Committee approval. No change to coverage.
10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. No change to coverage.
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval. No change to coverage.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. Policy statements changed to remove investigational statement for partially implantable devices.

01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
10/05/2017	Medical Policy Committee review
10/18/2017	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2018	Coding update
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. No change to coverage.
10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/04/2021	Medical Policy Committee review
02/10/2021	Medical Policy Implementation Committee approval. New FDA approved devices added to policy. Criteria revised to "For transcutaneous devices, A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kilohertz (kHz) of better than or equal to 45 decibel (dB) (BAHA Attract and Sophono (passive) devices) or 55 decibel (dB) (Cochlear Osia and Med-El Bonebridge (active) devices).
02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. No change to coverage.
12/07/2022	Coding update
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. No change to coverage.
02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. No change to coverage.
07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. Added "Based on review of available data, the Company may consider FDA-approved non-osseointegrated hearing device including a headband or other means of external attachment (**e.g.,** BAHA Soft Band, BAHA SoundArc, or MED-EL Adhere) when above selection criteria for bone-anchored hearing aids (osseointegrated) are met, to be eligible for coverage."

Added *"Note: This requirement is applicable only to adults age 18 or older with adult hearing aid benefits. Hearing aid benefit limitations apply to non-osseointegrated hearing devices. Non-osseoinegrated hearing devices are not covered under plans that exclude coverage of hearing aids."*
Added "Based on review of available data, the Company considers non-osseointegrated hearing devices when patient selection criteria are not met to be investigational". FDA information updated.

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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Implantable Bone-Conduction and Bone-Anchored Hearing Aids

Policy # 00004
Original Effective Date: 06/24/2002
Current Effective Date: 08/12/2024

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	69710, 69711, 69714, 69717, 69716, 69719, 69726, 69727, 69728, 69729, 69730, 69799
HCPCS	L8625, L8690, L8691, L8693, L8694 Add code effective 08/01/2024: L8692
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.