



# Louisiana

## **Implantable Bone-Conduction and Bone-Anchored Hearing Aids**

**Policy #** 00004

**Original Effective Date:** 06/24/2002

**Current Effective Date:** 11/09/2020

*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 patients 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 patients 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 patients 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

- 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 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 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.

## 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 patients with bilateral sensorineural hearing loss, 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**.\*

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### **Policy Guidelines**

In patients being considered for implantable bone-conduction (bone-anchored) hearing aid(s), skull bone quality and thickness should be assessed for adequacy to ensure implant stability. Additionally, patients (or caregivers) must be able to perform proper hygiene to prevent infection and ensure the stability of the implants and percutaneous abutments.

### **Background/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 ( $\geq 80$  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 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 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

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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).

Product codes: MAH, LXB

**Table 1. Implantable Bone-Conduction Hearing Systems Approved by the FDA**

| Device   | Manufacturer      | Date Cleared | 510(k) No. |
|--|-------------------|--------------|------------|
| Baha <sup>®</sup> ‡ Auditory Osseointegrated ImplantSystem | Cochlear Americas |              |            |
| BA310 Abutment, BIA310 Implant/Abutment                    |                   | Dec 2018     | K182116    |
| Baha 5 Power Sound Processor                               |                   | May 2016     | K161123    |

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|   |                |                      |                    |
|---|----------------|----------------------|--------------------|
| Baha 5 Super Power Sound Processor                      |                | Mar 2016             | K153245            |
| Baha <sup>®</sup> ‡ 5 Sound Processor                   |                | Mar 2015             | K142907            |
| Baha <sup>®</sup> ‡ Attract System                      |                | Nov 2013             | K131240            |
| Baha <sup>®</sup> ‡ Cordelle II                         |                | Jul 2015<br>Apr 2008 | K150751<br>K080363 |
| Baha Divino <sup>®</sup> ‡                              |                | Aug 2004             | K042017            |
| Baha Intenso <sup>®</sup> ‡ (digital signal processing) |                | Aug 2008             | K081606            |
| Baha <sup>®</sup> ‡ 4 (upgraded from the BP100)         |                | Sep 2013             | K132278            |
| OBC Bone-Anchored Hearing Aid System                    | Oticon Medical | Nov 2011             | K112053            |
| Ponto Bone-Anchored Hearing System                      | Oticon Medical | Sep 2012             | K121228            |
| Ponto 4   |                | May 2019             |                    |
| Ponto 3, Ponto 3 Power and Ponto 3 SuperPower           |                | Sep 2016             | K161671            |

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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<sup>®</sup> Softband<sup>™</sup>. 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. The FDA also cleared 2 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 FDA**

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

The SoundBite<sup>™</sup> 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.



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

### **Rationale/Source**

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.

For individuals who have conductive or mixed hearing loss who receive an implantable 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 an RCT, multiple prospective and retrospective case series, and a systematic review. Relevant outcomes are functional

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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. Quality RCTs on BAHA for unilateral sensorineural hearing loss are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

For patients with single-sided sensorineural deafness, a binaural hearing benefit may be provided by way of contralateral routing of signals to the hearing ear. There is evidence that bilateral hearing assistance devices improve hearing to a greater degree than unilateral devices. BAHAs may be considered an alternative to external devices in patients who are not candidates for external devices. By extension, the use of an implantable bone-conduction device with contralateral routing of the signal may be considered medically necessary in patients with unilateral sensorineural deafness.

## **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.

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.

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### Practice Guidelines and Position Statements

In 2016, 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, 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.”

### 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 unpublished trials that might influence this review are listed in Table 3.

**Table 3. Summary of Key Trials**

| <i>NCT No.</i>     | <i>Trial Name</i> | <i>Planned Enrollment</i> | <i>Completion Date</i> |
|--------------------|-------------------|---------------------------|------------------------|
| <i>Unpublished</i> |                   |                           |                        |

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|                          |  |     |   |
|--------------------------|--|-----|---|
| NCT01858246              | A Randomised Controlled Trial Comparing Bone Anchored Hearing Aid With Bonebridge  | 60  | Dec 2017<br><br>(Completed, last updated 2018)                  |
| NCT02092610 <sup>a</sup> | Long Term Stability, Survival and Tolerability of a (Novel) Baha® Implant System   | 77  | Mar 2015<br><br>(Completed, last updated 2016)                  |
| NCT01264510              | The Evaluation of the Effectiveness of Bone-anchored Hearing Aids (Baha) in Patients With Conductive or Mixed Hearing Loss, or Unilateral Deafness | 150 | Aug 2015<br><br>(Recruitment status unknown, last updated 2014) |
| NCT02022085 <sup>a</sup> | Post-market Clinical Follow-up of a Magnetic Bone Conduction Implant (Cochlear Baha Attract System)  | 2   | Nov 2017<br>(Completed, last updated 2018)                      |

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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### **Policy History**

Original Effective Date: 06/24/2002

Current Effective Date: 11/09/2020

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

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- 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

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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.

Next Scheduled Review Date: 10/2021

### **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 2019*

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*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.*

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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, 69715, 69717, 69718  |
| HCPCS            | L8625, L8690, L8691, L8693, L8694   |
| ICD-10 Diagnosis | H60.399, H60.60-H60.63, H60.8X1-H60.8X9, H60.90-H60.93, H61.391-H61.399, H62.8X1-H62.8X9, H65.20-H65.23, H65.30-H65.33, H65.411-H65.419, H65.491-H65.499, H66.001-H66.009, H66.011-H66.019, H66.10-H66.13, H66.20-H66.23, H66.3X1-H66.3X9, H66.40-H66.43, H66.90-H66.93, H67.1-H67.9, H90.0, H90.11-H90.12, H90.2, H90.6, H90.71-H90.72, H90.8, Q16.4 |

\*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

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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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

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**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.

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