Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 05/11/2020

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 psychological coping therapy including cognitive-behavioral therapy, self-help cognitive-behavioral therapy, tinnitus coping therapy, acceptance and commitment therapy, and psychophysiological treatment, for persistent and bothersome tinnitus, when self-help or internet-based coping therapies were ineffective, to be eligible for coverage.**

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 treatment of tinnitus with ANY of the following therapies to be investigational*:

- Biofeedback; OR
- Tinnitus maskers, customized sound therapy; OR
- Combined psychological and sound therapy (e.g., tinnitus retraining therapy); OR
- Transcranial magnetic stimulation; OR
- Transcranial direct current stimulation; OR
- Electrical transcutaneous electrical stimulation of the ear, electromagnetic energy; OR
- Transmeatal laser irradiation.

*For persistent and bothersome tinnitus
**In some cases, may be considered for patients with advanced tinnitus

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Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
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Note: This policy does not address surgical (e.g., cochlear or brainstem implant), pharmacologic treatment of tinnitus, (e.g., the use of amitriptyline or other tricyclic antidepressants), or injection of botulinum toxin.

Background/Overview

Tinnitus describes the perception of any sound in the ear in the absence of an external stimulus and presents as a malfunction in the processing of auditory signals. A hearing impairment, often noise-induced or related to aging, is commonly associated with tinnitus. Clinically, tinnitus is subdivided into subjective and objective types. The latter describes the minority of cases, in which an external stimulus is potentially heard by an observer (e.g., by placing a stethoscope over the patient’s external ear). Common causes of objective tinnitus include middle ear and skull-based tumors, vascular abnormalities, and metabolic derangements. The more common type is subjective tinnitus, which is frequently self-limited. In a small subset of patients with subjective tinnitus, its intensity and persistence leads to disruption of daily life. While many patients habituate to tinnitus, others may seek medical care if the tinnitus becomes too disruptive.

Treatment

Many treatments are supportive because, currently, there is no cure. One treatment, called tinnitus masking therapy, has focused on the use of devices worn in the ear that produce a broad band of continuous external noise that drowns out or masks the tinnitus. Psychological therapies may also be provided to improve coping skills, typically requiring 4 to 6 one-hour visits over an 18-month period. Tinnitus retraining therapy, also referred to as tinnitus habituation therapy, is based on the theories of Jastreboff, who proposed that tinnitus itself is related to the normal background electrical activity in auditory nerve cells, but the key factor in some patients’ unpleasant response to the noise is due to a spreading of the signal and an abnormal conditioned reflex in the extra-auditory limbic and autonomic nervous systems. The goal of tinnitus retraining therapy is to habituate (retrain) the subcortical and cortical response to the auditory neural activity. In contrast to tinnitus masking, the auditory stimulus is not intended to drown out or mask the tinnitus but is set at a level such that the tinnitus can still be detected. This strategy is thought to enhance extinction of the subconsciously conditioned reflexes connecting the auditory system with the limbic and autonomic nervous systems by increasing neuronal activity within the auditory system. Treatment may also include the use of hearing aids to increase external auditory stimulation. The Heidelberg model uses an intensive
Treatment of Tinnitus

Policy #   00127
Original Effective Date:   09/18/2002
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program of active and receptive music therapy, relaxation with habituation to the tinnitus sound, and stress mapping with a therapist.

Sound therapy is a treatment approach based on evidence of auditory cortex reorganization (cortical remapping) with tinnitus, hearing loss, and sound/frequency training. One type of sound therapy uses an ear-worn device (Neuromonics Tinnitus Treatment) prerecorded with selected relaxation audio and other sounds spectrally adapted to the individual patient’s hearing thresholds. This is achieved by boosting the amplitude of those frequencies at which an audiogram has shown the patient to have a reduced hearing threshold. Also being evaluated is auditory tone discrimination training at or around the tinnitus frequency. Another type of sound therapy being investigated uses music with the frequency of the tinnitus removed (notched music) to promote reorganization of sound processing in the auditory cortex. One theory behind the notched music is that tinnitus is triggered by injury to inner ear hair cell population, resulting in both a loss of excitatory stimulation of the represented auditory cortex and loss of inhibition on the adjoining frequency areas. It is proposed that this loss of inhibition leads to hyperactivity and overrepresentation at the edge of the damaged frequency areas and that removing the frequencies overrepresented at the audiometric edge will result in the reorganization of the brain.

Electrical stimulation to the external ear has also been investigated and is based on the observation that electrical stimulation of the cochlea associated with a cochlear implant may be associated with a reduction in tinnitus. Transcranial magnetic stimulation, electrical stimulation, and transmeatal low-power laser irradiation have also been evaluated.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
The Neuromonics® Tinnitus Treatment is one of many tinnitus maskers cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. It is “…intended to provide relief from the disturbance of tinnitus while using the system, and with regular use (over several months) may provide relief to the patient whilst not using the system.” Food and Drug Administration product code: KLW.
# Treatment of Tinnitus

Policy # 00127  
Original Effective Date: 09/18/2002  
Current Effective Date: 05/11/2020

## Table 1. Devices Cleared by the US Food and Drug Administration

<table>
<thead>
<tr>
<th>Devices</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tinnitus Sound Generator Module</td>
<td>Gn Hearing A/S</td>
<td>11/30/2018</td>
<td>K180495</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Audifon Tinnitus-Module</td>
<td>Audiofon Usa Inc.</td>
<td>10/19/2017</td>
<td>K171243</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Tinnilogic Mobile Tinnitus Management De</td>
<td>Jiangsu Betterlife Medical Co., Ltd.</td>
<td>5/17/2017</td>
<td>K163094</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Sound Options Tinnitus Treatment</td>
<td>Sound Options Tinnitus Treatments Inc.</td>
<td>9/28/2016</td>
<td>K161562</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Hypersound Tinnitus Module</td>
<td>Turtle Beach Corporation</td>
<td>8/23/2016</td>
<td>K161331</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Desyncra For Tinnitus Therapy System, De</td>
<td>Neurotherapies Reset GmbH.</td>
<td>1/20/2016</td>
<td>K151558</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Reve134</td>
<td>Kw Ear Lab, Inc.</td>
<td>10/9/2015</td>
<td>K151719</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Serenity</td>
<td>Sanuthera, Inc.</td>
<td>7/27/2015</td>
<td>K150014</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Soundcure Serenade Tinnitus Treatment Sy</td>
<td>Soundcure, Inc.</td>
<td>4/13/2015</td>
<td>K150065</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Levo Tinnitus Masking Software Device</td>
<td>Otoharmonics Corp.</td>
<td>7/18/2014</td>
<td>K140845</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Solace Sound Generators</td>
<td>Amplisound Hearing Products &amp; Services</td>
<td>3/25/2014</td>
<td>K132965</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Tinnitus Soundsupport</td>
<td>Oticon A/S</td>
<td>3/18/2014</td>
<td>K133308</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Wave 2g, Soul</td>
<td>Hansaton Akustik GmbH</td>
<td>1/3/2014</td>
<td>K130937</td>
<td>Tinnitus Relief</td>
</tr>
</tbody>
</table>
Rationale/Source

Various nonpharmacologic treatments are being evaluated to improve the symptoms of tinnitus. These approaches include psychological coping therapies, sound therapies, combined psychological and sound therapies, repetitive transcranial magnetic stimulation, electrical and electromagnetic stimulation, and transmeatal laser irradiation.

For individuals who have persistent, bothersome tinnitus who receive psychological coping therapy, the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. These therapies are intended to reduce tinnitus impairment and improve health-related quality of life. Meta-analyses of a variety of cognitive and behavioral therapies have found improvements in global tinnitus severity and quality of life, even when tinnitus loudness is not affected. Other RCTs have reported that a self-help/Internet-based approach to cognitive and behavioral therapy or acceptance and commitment therapy may also improve coping skills. The evidence is sufficient to determine that the technology results in a meaningful improvement in health outcomes.

For individuals who have tinnitus who receive sound therapy, the evidence includes RCTs and a systematic review of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on tinnitus masking includes RCTs and a systematic review of RCTs. The RCTs had medium-to-high risk of bias and did not show the efficacy of masking therapy. Research on customized sound therapy appears to be at an early stage. For example, the studies described the use of very different approaches for sound therapy, and it is not yet clear whether therapy is more effective when the training frequency is the same or adjacent to the tinnitus pitch. A 2016 trial, double-blinded and adequately powered, found no benefit of notched music on the primary outcome measures of tinnitus perception and tinnitus distress, although the subcomponent score of tinnitus loudness was reported to be reduced. A benefit on tinnitus loudness but not tinnitus perception or tinnitus distress is of uncertain clinical significance, may be spurious, and would need corroboration in additional studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have tinnitus who receive combined psychological and sound therapy, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on tinnitus retraining therapy consists of a number of
small randomized or quasi-RCTs. Collectively, the literature does not show consistent improvements in the primary outcome measure (Tinnitus Handicap Inventory scores) when tinnitus retraining therapy is compared with active or sham controls. For Heidelberg neuromusic therapy, a trial has used an investigator-blinded RCT design and showed positive short-term results following treatment. However, the durability of treatment is also unknown. A large, multicenter RCT trial using an intensive, multidisciplinary intervention showed improvement in outcomes. However, it is uncertain whether the multiple intensive interventions used in this trial could be replicated outside of the investigational setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have tinnitus who receive transcranial magnetic stimulation, the evidence includes a number of small- to moderate-sized RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Results from these studies are mixed, with some trials reporting a statistically significant effect of repetitive transcranial magnetic stimulation on tinnitus severity and others reporting no significant difference. Larger controlled trials with longer follow-up are needed for this common condition. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have tinnitus who receive electrical or electromagnetic stimulation, the evidence includes a number of sham-controlled randomized trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The available evidence does not currently support the use of these stimulation therapies. A 2015 sham-controlled study that was adequately powered found no benefit of transcranial direct current stimulation. Moreover, while a 2017 meta-analysis found some benefit for transcranial direct current stimulation, it was noted that further study would be needed to evaluate transcranial direct current stimulation as a treatment option. Studies have not shown a benefit for direct current electrical stimulation of the ear. The evidence on electromagnetic energy includes a small RCT, which found no benefit for the treatment of tinnitus. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have tinnitus who receive transmeatal laser irradiation, the evidence includes RCTs and crossover trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence for transmeatal laser irradiation includes a number of
Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 05/11/2020

double-blind RCTs, most of which showed no treatment efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Supplemental Information**

**Practice Guidelines and Position Statements**

**International Federation of Clinical Neurophysiology**
The International Federation of Clinical Neurophysiology sponsored evidence-based guidelines (2017) on the use of transcranial direct current stimulation (tDCS). The guidelines did not recommend tDCS as a treatment for tinnitus because studies suggested anodal tDCS of the left temporoparietal cortex was probably ineffective (level B evidence). A lack of data precluded any recommendation on the use of tDCS of the left dorsolateral prefrontal cortex as therapy for chronic tinnitus.

**American Academy of Otolaryngology – Head and Neck Surgeons**
In 2014 the American Academy of Otolaryngology – Head and Neck Surgeons published evidence-based guidelines on tinnitus.

<table>
<thead>
<tr>
<th>Table 2. Guidelines on Treatment of Tinnitus</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommendation</strong></td>
</tr>
<tr>
<td>“Clinicians must differentiate patients with bothersome tinnitus from patients with nonbothersome tinnitus”</td>
</tr>
<tr>
<td>“Clinicians should distinguish patients with bothersome tinnitus of recent onset from those with persistent symptoms (≥ 6 months) to prioritize intervention and facilitate discussion about natural history and follow-up care”</td>
</tr>
<tr>
<td>“Clinicians may recommend sound therapy to patients with persistent, bothersome tinnitus”</td>
</tr>
<tr>
<td>“Clinicians should recommend cognitive behavioral therapy to patients with persistent, bothersome tinnitus”</td>
</tr>
<tr>
<td>“Clinicians should not routinely recommend antidepressants, anticonvulsants, anxiolytics, or intratympanic medications for a primary indication of treating persistent, bothersome tinnitus”</td>
</tr>
</tbody>
</table>
Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 05/11/2020

“Clinicians should not recommend transcranial magnetic stimulation for the routine treatment of patients with persistent, bothersome tinnitus”

GOE: grade of evidence; SOR: strength of recommendation.

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

Medicare National Coverage
The Centers for Medicare & Medicaid Services had a longstanding national coverage determination for tinnitus masking, which was retired in 2014.

Ongoing and Unpublished Clinical Trials

Table 3. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02370810</td>
<td>Study Protocol for a CBT-based Internet Intervention for Adults With Tinnitus in the United Kingdom: A Randomised Controlled Trial</td>
<td>160</td>
<td>Sep 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT02665975</td>
<td>Internet-based Versus Face-to-face Clinical Care for Tinnitus: A Multi-study Randomised Control Trial</td>
<td>80</td>
<td>Nov 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT02438891</td>
<td>Evaluation of an Internet-based Sound and Cognitive Behavioral Therapy Course for Treatment for Tinnitus</td>
<td>200</td>
<td>Jul 2018</td>
</tr>
<tr>
<td>NCT03026829a</td>
<td>“Cochlear Active Relief From Tinnitus (CART) Sound Therapy” for Tinnitus Relief in Nucleus®‡ Cochlear Implant Users With Tinnitus</td>
<td>50</td>
<td>Feb 2019</td>
</tr>
<tr>
<td>NCT02794623</td>
<td>Evaluation of Tinnitus Suppression for Cochlear Implant Recipients</td>
<td>14</td>
<td>Aug 2019</td>
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<tr>
<td>NCT03022084</td>
<td>Clinical Trial of Sound-Based Versus Behavioral Therapy for Tinnitus</td>
<td>61</td>
<td>Dec 2019</td>
</tr>
</tbody>
</table>
Treatment of Tinnitus

Policy #   00127
Original Effective Date:   09/18/2002
Current Effective Date:   05/11/2020

NCT03114878 The Value of Eye Movement Desensitization Reprocessing in the Treatment of Tinnitus 166 Dec 2019
NCT02071732 Repetitive Transcranial Magnetic Stimulation (rTMS) Effect on Tinnitus 40 Dec 2019
NCT00926237 Effect of rTMS on Resting State Brain Activity in Tinnitus 60 Sep 2020

Unpublished
NCT02408575 Hearing Aids With "Notched Amplification" for the Treatment of Chronic Tinnitus - A Controlled Randomized Pilot Study on Safety, Tolerability and Clinical Performance 44 Jun 2016 (completed)
NCT01929837 Treatment of Tinnitus With Transcranial Magnetic Stimulation 80 Aug 2016 (completed)
NCT02293512 A Comparison of CBT and CET Interventions for Veterans With Tinnitus 40 Nov 2016 (completed)
NCT01177137 Tinnitus Retraining Therapy Trial 151 Feb 2017 (completed)

Unpublished
NCT03068871 A Comparison of Two Psycho-educational Group Interventions for Tinnitus Patients 45 July 2017 (completed)
NCT02653547 Influence of Treatment Duration and Stimulation Frequency on Repetitive Transcranial Magnetic Stimulation in Chronic Tinnitus 80 May 2018 (Completed)

NCT: national clinical trial.
a Denotes industry-sponsored or co-sponsored trial.

References

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Treatment of Tinnitus

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Current Effective Date: 05/11/2020


Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 05/11/2020


Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 05/11/2020


Policy History
Original Effective Date: 09/18/2002
Current Effective Date: 05/11/2020
09/11/2002 Medical Director review
09/18/2002 Managed Care Advisory Council approval
10/05/2004 Medical Director review
11/16/2004 Medical Policy Committee review

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Treatment of Tinnitus

Policy #  00127
Original Effective Date:  09/18/2002
Current Effective Date:  05/11/2020

Format revision. Policy amended to include transmeatal irradiation as investigational.
11/29/2004  Managed Care Advisory Council approval.
07/07/2006  Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
11/01/2006  Medical Director review
11/15/2006  Medical Policy Committee approval. Coverage eligibility updated. Additional techniques in the treatment of tinnitus are also considered investigational: Electromagnetic energy, transcranial magnetic stimulation and Botulinum toxin A.
11/05/2008  Medical Director review
11/18/2008  Medical Policy Committee approval. No change to coverage.
11/12/2009  Medical Policy Committee approval
11/04/2010  Medical Policy Committee review
11/03/2011  Medical Policy Committee review
11/01/2012  Medical Policy Committee review
11/28/2012  Medical Policy Implementation Committee approval. No change to coverage.
11/07/2013  Medical Policy Committee review
11/20/2013  Medical Policy Implementation Committee approval. No change to coverage.
11/06/2014  Medical Policy Committee review
08/03/2015  Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015  Medical Policy Committee review
11/16/2015  Medical Policy Implementation Committee approval. No change to coverage.
11/03/2016  Medical Policy Committee review
11/16/2016  Medical Policy Implementation Committee approval. Transcranial direct current stimulation added to investigational statement.
Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 05/11/2020

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
04/06/2017 Medical Policy Committee review
04/19/2017 Medical Policy Implementation Committee approval. Added coverage statement for psychological coping therapy for tinnitus and removed tinnitus retraining therapy, tinnitus coping therapy and botulinum toxin A injections from investigational statement.
04/05/2018 Medical Policy Committee review
04/18/2018 Medical Policy Implementation Committee approval. Biofeedback added to investigational list. Eligible for coverage statement changed to “Based on review of available data, the Company may consider psychological coping therapy including cognitive-behavioral therapy, self-help cognitive-behavioral therapy, tinnitus coping therapy, acceptance and commitment therapy, and psychophysiological treatment, for persistent and bothersome tinnitus, when self-help or internet-based coping therapies were ineffective, to be eligible for coverage.”
04/04/2019 Medical Policy Committee review
04/24/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/02/2020 Medical Policy Committee review
04/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2021

Coding

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Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 05/11/2020

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

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
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<tbody>
<tr>
<td>CPT</td>
<td>97014, 97026, 97032</td>
</tr>
<tr>
<td>HCPCS</td>
<td>C1816, C1883, E0720, E0761, S8948</td>
</tr>
</tbody>
</table>

*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:
Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 05/11/2020

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.

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