



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 04/18/2018

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

Note: This policy does not address surgical (eg, 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

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 (eg, 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.

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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 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.

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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. FDA 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." FDA product code: KLW.

Centers for Medicare and Medicaid Services (CMS)

The CMS had a longstanding national coverage determination for tinnitus masking, which was retired in 2014.

Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

TINNITUS TREATMENT OVERVIEW

In 2013, the Agency for Healthcare Research and Quality published a comparative effectiveness review on assessment and treatment of tinnitus. Treatments evaluated included laser, transcranial magnetic stimulation, hyperbaric oxygen therapy, sound treatments, and psychological/behavioral treatments. Studies met inclusion criteria if they had a comparator or control treatment, which could include placebo, no treatment, waiting-list, treatment as usual, or other intervention. Eleven studies selected focused on medical interventions, 4 on sound technology interventions, and 19 on psychological and behavioral interventions. Reviewers found insufficient evidence for medical and sound technology interventions. For psychological and behavioral interventions, there was low-level evidence for an effect of cognitive-behavioral therapy (CBT) on tinnitus-specific quality of life (QOL), and low-level evidence for no effect of CBT on subjective

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loudness, sleep disturbance, anxiety, depression, and global QOL. Evidence was insufficient for other psychological and behavioral interventions such as tinnitus retraining therapy and relaxation.

PSYCHOLOGICAL COPING THERAPY

A 2010 Cochrane review included 8 trials with a total of 468 participants (see Table 1). Inclusion criteria for all but 1 trial included the presence of symptoms for at least 6 months and subjective impairment or annoyance. The experimental groups included CBT, self-help CBT, tinnitus coping therapy, psychophysiological treatment, and biofeedback. There were no significant differences in subjective tinnitus loudness between psychological therapies and either no treatment or another intervention, but there was an improvement in QOL associated with decreased global tinnitus severity. The analysis found evidence that depression scores improved when comparing CBT with no treatment, but there was no evidence of benefit in depression scores when compared with other treatments (yoga, education, minimal contact education).

Table 1. Characteristics of a Meta-Analysis of Randomized Controlled Trials

| Study | Groups | N | Inclusion Criteria |
|----------------------------|--------------------------------------|-----|--------------------------------------|
| Andersson et al (2005) | CBT, waitlist | 23 | |
| Henry et al (1996) | CBT, education, waitlist | 60 | ≥17 points on TRQ |
| Kaldo et al (2007) | Self-help CBT, waitlist | 72 | ≥10 points on TRQ |
| Kroner-Herwig et al (1995) | CBT, yoga, waitlist | 43 | >4 of 10-point scale for impairment |
| Kroner-Herwig et al (2003) | TCT, education, relaxation, waitlist | 95 | >40 of 100-point scale for annoyance |
| Rief et al (2005) | Psychophysiological, waitlist | 43 | >3 of 10-point scale for annoyance |
| Weise et al (2008) | Biofeedback, waitlist | 111 | ≥47 points on TQ |
| Zachriat et al (2004) | TCT, habituation, education | 77 | >25 on TQ |

Adapted from Martinez-Devesa et al (2010). CBT: cognitive-behavioral therapy; TCT: tinnitus coping therapy; TQ: Tinnitus Questionnaire; TRQ: Tinnitus Reaction Questionnaire.

Cognitive-Behavioral Therapy

Zenner et al (2013) reported on a multicenter pragmatic trial comparing a standardized, individual, tinnitus-specific CBT program with a waiting-list control in 286 patients between 14 and 78 years of age. Four sites enrolled patients into the CBT program, while a fifth site enrolled patients into the waiting-list control group. There were differences between groups at baseline for tinnitus compensation, tinnitus quality, and tinnitus duration. Also, the intervention group was assessed at a median of 10 weeks while the control group was assessed at a median of 24 weeks. The primary outcome measure (tinnitus change score using an 8-point numeric, verbal rating scale) showed treatment efficacy (odds ratio, 3.4; 95% confidence interval [CI], 2.6 to 4.5) in intention-to-treat analysis. Improvement in the tinnitus change score by 2 or more points was reported by 84% of CBT-treated patients compared with 22% of controls. Another primary outcome—the composite of tinnitus change, loudness, and annoyance scores, and Tinnitus Questionnaire (TQ) score—improved significantly more in the treatment group than in the control group. The TQ is a validated, 52-item self-rating scale that assesses emotional and cognitive distress, intrusiveness, auditory perceptual difficulties, sleep disturbance, and somatic complaints. Tinnitus change, loudness, and

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annoyance scales appear to have been developed and tested for validity in a prior study by the authors of this report.

Acceptance and Commitment Therapy

Westin et al (2011) reported on an RCT comparing acceptance and commitment therapy (ACT) with tinnitus retraining therapy or waiting-list control in 64 patients with normal hearing. The ACT group (n=22) received retraining consisting of 10 weekly 60-minute sessions; the tinnitus retraining group (n=20) received one 150-minute session, one 30-minute follow-up, and continued use of sound generators during waking hours for 18 months; the control group was allocated to a wait-list (n=22). The primary outcome measure was the Tinnitus Handicap Inventory (THI), with assessments at baseline, 10 weeks, 6 months, and 18 months. There was a significant advantage of ACT over tinnitus retraining over time. In the ACT group, THI scores improved from 45.27 at baseline to 28.19 at 18 months. In the tinnitus retraining group, THI score improved from 47.00 at baseline to 41.86 at 18 months, while the waiting-list control was unchanged at 48.29. THI scores were significantly improved in the ACT group (54.5%) compared with the tinnitus retraining group (20%; $p < 0.04$).

Self-Help and Internet-Based Coping Therapies

An RCT by Kaldo et al (2007) found that a CBT self-help book for tinnitus combined with 7 weekly phone calls from a therapist reduced distress ($\geq 50\%$ on the Tinnitus Reaction Questionnaire [TRQ] scores) in 32% of 34 subjects compared with 5% of 38 waiting-list controls. Analysis of follow-up data suggested that a self-help book alone (provided to the control group after the study period) without therapist support might result in equivalent improvement in distress because 26% to 28% of patients from both groups showed distress reduction at 1 year. A subsequent RCT by Kaldo et al (2008) found that an Internet-based self-help program was as effective as standardized group-based CBT for reducing tinnitus distress.

These RCTs were followed by a 2012 RCT of Internet-based CBT or ACT. Ninety-nine participants with moderate-to-severe tinnitus distress were recruited from the community and randomized to guided, self-help CBT (n=32) or ACT (n=35) or to a control condition of a monitored Internet discussion forum on tinnitus (n=32). Assessment at 8 weeks showed improvement for both of the psychological therapies compared with controls, with no significant difference between CBT and ACT. Follow-up at 1 year was conducted for the 2 psychological therapies, which remained improved over baseline. There was no follow-up at 1 year for controls.

An RCT by Jasper et al (2014) followed a similar design, with 128 patients randomized to group CBT (GCBT; n=43), Internet-based CBT (ICBT; n=41), or a web-based discussion forum that represented the control condition (n=44). Both CBT interventions resulted in significant improvements in the primary outcome measures of THI and Mini-TQ scores, with no significant differences between the 2 groups. A clinically relevant response on the THI, defined as a 14-point improvement, was found for 41% of the ICBT participants and 50% of the GCBT participants at the conclusion of treatment. At 6-month follow-up, the responder rate was 49% for ICBT and 51% for GCBT. A responder analysis was not reported for the control group. The amount of time therapists spent with each patient was similar for both CBT groups, with an

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average of 11 messages sent and 9 received in the ICBT group and an average of 10 participants in each 90-minute weekly session for GCBT. A greater percentage of patients considered GCBT to be more effective than ICBT, and more GCBT patients were satisfied with their treatment.

Similarly, Weise et al (2016) randomized 124 patients with severe tinnitus-related distress to therapist-guided ICBT or a moderated online discussion forum. For the primary outcome of tinnitus-related distress, there was a significant interaction of time by a group that was supported by large effect sizes (THI standardized effect size, 0.83; 95% CI, 0.47 to 1.20; TQ standardized effect size, 1.08; 95% CI, 0.71 to 1.64). For the secondary outcomes, Hospital Anxiety and Depression Scale, Tinnitus Acceptance Questionnaire, and Insomnia Severity Index, small-to-medium effect sizes (ES) were found. Benefits in the ICBT group were clinically significant and maintained at 6-month and 1-year follow-ups. Strengths of this trial included power calculations and adequate follow-up rates, along with randomization by an independent researcher. However, neither patients nor evaluators were blinded to treatment condition, and the control group crossed over to ICBT after the treatment period, limiting interpretation of the 6-month and 1-year follow-ups.

Beukes et al (2017) randomized (1:1) 146 individuals with tinnitus to 8 weeks of Internet-based cognitive behavior therapy guided by an audiologist or to a control group, which received the therapy after the experimental group. Among several assessment measures given to the groups (which included a number of questionnaires), the primary measure of interest was the Tinnitus Functional Index (TFI) score. At baseline, the mean TFI score was similar between the experimental (59.8) and control (59.2) groups; given a clinically significant reduction of 23.3 points, over half of the experimental group (51%) experienced such a reduction, compared with 5% of the control group following the initial 8 weeks of the study. Secondary measures were assessed by the following questionnaires: Insomnia Severity Index, Patient Health Questionnaire, Hyperacusis Questionnaire, Cognitive Failures Questionnaire, Satisfaction with Life Scales, Generalized Anxiety Disorder scale, and Hearing Handicap Inventory for Adults–Screening version. For all but the last 2 measures listed (anxiety and hearing disability), significant improvements were observed for varying percentages of the experiment group, especially from the fourth week of treatment to its end. The authors acknowledged several limitations, among them the lack of data regarding treatment credibility and the inclusion of several questionnaires without psychometric validation. Also, the patients were not identified in a clinical setting, but responded to a general call for participants with tinnitus; finally, only 73% of the experimental group and 82% of the control group remained to the study's completion at 2 months.

Also employing the TFI, Henry et al (2017) assessed the relative efficacy of several types of hearing aid devices (all manufactured by Phonak) worn by persons with tinnitus. Fifty-five participants were randomized and instructed to bilaterally wear the devices for 4 months: extended-wear hearing aids (n=18), traditional receiver-in-the-canal hearing aids (HA [n=18]), and receiver-in-the-canal hearing aids with a sound generator (n=19). Most participants experienced reductions in their tinnitus symptoms. Clinically significant improvement was noted in all groups: 67% saw improvement in the HA set, 79% in hearing aids with a sound generator, and 82% in the HA set. Improvement was prespecified as a 13-point reduction in TFI score. On average, the HA set reported a 21-points reduction; the extended-wear hearing aids set a 31-

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point reduction; and the hearing aids with a sound generator set a 33-point reduction. While each device provided tinnitus symptom relief, no single hearing aid proved statistically to be better than the other.

Section Summary: Psychological Coping Therapy

The evidence on the use of psychological coping therapies in patients who have persistent, bothersome tinnitus includes a number of RCTs and meta-analyses of RCTs. These therapies are intended to reduce tinnitus impairment and improve health-related QOL. Meta-analyses of a variety of cognitive and behavioral therapies had reported improvements in global tinnitus severity and QOL, even when tinnitus loudness was not affected. There is some evidence that self-help and Internet-based therapies may be as effective as traditional group therapy with ACT and CBT, although patients may have greater satisfaction with group treatment. Overall, the literature indicates that psychological therapies can improve coping skills and QOL and decrease tinnitus-associated distress and annoyance compared with wait-listed controls.

SOUND THERAPY

Tinnitus Masking

A 2010 Cochrane review, updated in 2012, evaluated the evidence for masking in the management of tinnitus in adults. Selected were 6 RCTs (total N=553 participants) that used noise-generating devices or hearing aids as the sole management tool or in combination with other strategies, including counseling. Heterogeneity in outcome measures precluded meta-analysis of the data. The risk of bias was medium in 3 studies and high in 3 studies. Reviewers concluded that, due to the lack of quality research and the common use of combined approaches (hearing therapy plus counseling), the limited data failed to show evidence of the efficacy of masking therapy in tinnitus management. A 2015 study of preferences for hearing aids and tinnitus maskers among Iran-Iraq War veterans who had blast-induced chronic tinnitus found that, after 2 years, 84% of the 974 patients preferred just a hearing aid, 2.7% chose the noise generator, and the rest preferred to use both devices.

Customized Sound Therapy

Four randomized or pseudorandomized controlled trials were identified on a variety of methods of customized sound therapy. These trials are discussed by the type of sound therapy.

Neuromonics Tinnitus Treatment

A 2008 industry-sponsored randomized study compared treatment with a proprietary customized acoustic stimulus for tinnitus retraining or counseling alone. Fifty (of 88 subjects recruited) were found to meet the inclusion and exclusion criteria. Mean length of time that tinnitus bothered patients was 3.6 years (range, 0.2-23 years). Patients were allocated to 1 of 4 groups, (1) customized acoustic stimulus at high intensity for 2 hours a day, (2) customized acoustic stimulus at a lower intensity, (3) tinnitus retraining therapy with a broadband stimulator and counseling, or (4) counseling alone. Subjects were instructed to listen to the devices for 2 hours a day at the time of day when symptoms were most severe and at a level that completely (group 1) or partially (group 2) masked the tinnitus; device use averaged 1.8 hours a day (range, 0.4-6.8 h/d). The 2 customized acoustic stimuli groups were combined in the analysis due to overlap in the self-administered stimulus intensity (absence of statistical difference between groups). All patients lost to

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follow-up were included in the dataset for analysis using the last value carried forward method. Mean TRQ scores improved for the combined customized acoustic stimuli group over the 12 months of the study. TRQ scores did not improve significantly in the control groups. At 6-month follow-up, 86% of patients in the combined acoustic stimuli group had met the definition of success based on 40% improvement in TRQ scores. Normalized visual analog scale scores for tinnitus severity, general relaxation, and loudness tolerance were improved relative to both baseline and the control group's scores at 12 months. Perceived benefits were also greater with the customized acoustic stimulus.

Another 2008 publication from the developers of the same acoustic device described results for the first 552 patients who received treatment at specialized clinics in Australia. Patients were divided into three levels, based on complicating factors and proposed suitability for the treatment. Tier 1 (237 patients) did not display any nonstandard or complicating factors. Tier 2 (223 patients) exhibited one or more of the following: psychological disturbance, a low-level of tinnitus-related disturbance (TRQ score <17), and/or moderately severe or severe hearing loss in 1 ear (>50 dB). Tier 3 (92 patients) exhibited one or more of the following: "reactive" tinnitus, continued exposure to high levels of noise during treatment, active pursuit of compensation, multitone tinnitus, pulsatile tinnitus, Meniere disease, and/or hearing loss of greater than 50 dB in both ears. Of the 552 patients who began therapy, 62 (11%) discontinued treatment, and 20 (4%) were lost to follow-up. After an average treatment duration of 37 weeks, TRQ scores improved (>40%) in 92% of tier 1 patients, in 60% of tier 2 patients, and in 39% of tier 3 patients. Investigators did not report whether the reduction in symptoms persisted when treatment stopped. Controlled studies with long-term follow-up would be needed to evaluate the durability of treatment and the relative contribution to these results of generalized masking vs desensitization.

Auditory Discrimination Training

Herraiz et al (2010) randomized 45 patients who scored mild or moderate (<56) on the THI to auditory discrimination training with the same frequency as the tinnitus pitch or training on a frequency near to but not the same as the tinnitus pitch. An additional 26 patients were included in a waiting-list control group. Auditory discrimination consisted of 20 minutes of training every day for 30 days, during which the patient had to record whether each stimulus pair was the same or different. Forty-one (91%) patients completed training and follow-up questionnaires. Four percent of patients in the waiting-list control group reported their tinnitus to be better compared with 42% of patients in the auditory discrimination training group. Self-reported improvement in tinnitus tended to be greater in the near to but not the same frequency as the tinnitus pitch group (54%) compared with the same frequency as the tinnitus pitch group (26%), although subjective improvement varied, and did not differ statistically. Subjective improvement in visual analog scale tinnitus intensity was modest and similar in both groups (0.65 vs 0.32, respectively). The decrease in THI scores was significantly greater in the patients near to but not the same as the tinnitus pitch frequencies (11.31) than in patients trained on the same as the tinnitus pitch frequencies (2.11; $p=0.035$).

Notched Music

In another publication, Okamoto et al (2010) reported on a small (N=24) double-blind, pseudorandomized trial that compared 12 months of listening to notched music (with the tinnitus frequency removed) with

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placebo music. An additional group of patients, unable to participate in the music training due to time constraints, served as a monitoring control. Thirty-nine patients who met the strict inclusion criteria were recruited; the final group sizes after dropouts and exclusions were 8 in the target-notched music group, 8 in the placebo group, and 7 in the monitoring group. After 12 months of music (≈ 12 h/wk), there was a significant decrease in tinnitus loudness ($\approx 30\%$) in the target-notched music group but not in the placebo or monitoring groups. Evoked activity to the tinnitus frequency, measured by magnetoencephalography, was also reduced in the primary auditory cortex of the target music group but not in the placebo or monitoring groups. Change in subjective tinnitus loudness and auditory-evoked response ratio correlated ($r=0.69$), suggesting an association between tinnitus loudness and reorganization of neural activity in the primary auditory cortex. Additional studies with a larger number of patients would be needed to evaluate this novel and practical treatment approach.

Stein et al (2016) reported on a double-blinded and adequately powered RCT of notched music training in 100 participants with tonal tinnitus. There was no restriction for age or magnitude of hearing loss, and randomization was stratified for these factors. Participants provided their preferred music and were advised to listen for 2 successive hours a day for 3 months. The active treatment removed one-half octave around the tinnitus frequency while amplifying the edge frequency bands by 20 dB. The placebo treatment consisted of music with a moving notch. The primary outcomes were tinnitus perception (loudness, annoyance, awareness, handicap) measured with total visual analog scale scores and tinnitus distress on the THQ. No effect was found for the primary outcome measures by intention-to-treat or per protocol analysis, although the subscale of tinnitus loudness was reported to be reduced.

Sound Options Tinnitus Treatments

Li et al (2016) reported on a double-blinded randomized evaluation of 12 months of at least 2 hours daily of classical music that was spectrally altered according to a proprietary computational model of the individual's auditory threshold and tinnitus characteristics (eg, tonal, ringing, hissing, primary frequency). Controls listened to unaltered classical music for the same period of time, and both groups were assessed at baseline and 2, 6, and 12 months after initial testing. The trial had a high loss to follow-up and was insufficiently powered, with only 34 (68%) of 50 patients completing the study. Three individuals dropped out before the baseline session, four dropped out during follow-up, and nine were excluded due to noncompliance with the study requirements, which may have been related to the limited (6-hour) selection of music. At 12 months, the difference between groups, controlling for baseline scores and treatment adherence, was -17.41 on the THI ($p=0.001$), with an ES of 0.60. The percentage of participants who were at least moderately handicapped by tinnitus (THI score ≥ 38) decreased from 60% to 33% in the treatment group but remained unchanged (at 63% in the control group). Scores did not differ significantly between groups for TFI or Hospital Anxiety and Depression Scale scores. Interpretation of this study was limited by the high dropout and noncompliance rates.

Section Summary: Sound Therapy

Sound therapies include tinnitus masking and customized sound therapy. The evidence on tinnitus masking includes a number of RCTs and a systematic review. The RCTs, which have a medium-to-high risk of bias,

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have not shown evidence of efficacy of masking therapy. Customized sound therapy has a solid neurophysiologic basis and the potential to substantially improve tinnitus symptoms; however, research in this area appears to be at an early stage. For example, the studies described use 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, or when it is altered based on the tinnitus characteristics. 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 subscale score of tinnitus loudness was reported to be reduced. A benefit on tinnitus loudness but not tinnitus perception or tinnitus distress is unusual and would need to be corroborated in additional studies.

COMBINED PSYCHOLOGICAL AND SOUND THERAPY

Tinnitus Retraining Therapy

A 2011 systematic review identified 3 RCTs evaluating tinnitus retraining therapy. One trial did not find an improvement over an education-only intervention, and two provided low-quality evidence for the efficacy of an individualized multicomponent intervention that included tinnitus retraining. Additional controlled studies are described next.

The RCT by Westin et al (2011; previously described) compared results of tinnitus retraining with ACT or waiting-list control in 64 patients with normal hearing. In this trial, tinnitus retraining was significantly less effective than ACT. The percentage of patients with reliable improvements was 54.5% in the ACT group and 20% in the tinnitus retraining group ($p < 0.04$), with 10% of patients in the tinnitus retraining group showing deterioration during the trial. In the tinnitus retraining group, THI scores improved from 47.00 at baseline to 41.86 at 18 months, while waiting-list control score remained unchanged at 48.29. Interpretation of these findings is limited by the lack of a placebo-control group.

Bauer and Brozoski (2011) reported on a pseudorandomized study of tinnitus retraining therapy in 32 patients with normal to near-normal hearing (75% follow-up). Group assignment was balanced by tinnitus severity on the THI, Beck Depression Inventory scores, and sex. Participants were assigned to 8 hours of daily tinnitus retraining with three 1-hour sessions of individual counseling on tinnitus retraining over 18 months, or a control arm of 3 counseling sessions that included coping techniques and sham sound therapy. Participants in the control arm were provided with a sound device and told to increase use to 8 hours a day, although the device ramped to off in 30 minutes. Participants were evaluated at 6, 12, and 18 months with a computerized test battery of questionnaires and psychophysical procedures. The primary outcome measure was THI score. Secondary outcome measures were change in global tinnitus impact, subjective tinnitus loudness rating, and objective tinnitus loudness measured by a psychophysical matching procedure. THI score improved over the 18 months to a similar extent for both the active and sham tinnitus retraining therapy groups. Subjective loudness was significantly reduced in the tinnitus retraining group compared with controls at 12 and 18 months ($p = 0.04$), but there were no between-group differences in the rating of annoyance and distress.

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Another pseudorandomized trial, from a Veterans Administration medical center, published in 2006, compared tinnitus masking with tinnitus retraining therapy. Following initial screening for tinnitus severity and motivation to comply with the 18-month study, 59 subjects were enrolled in the tinnitus masking condition (mean age, 61 years), and 64 were enrolled in tinnitus retraining (mean age, 59 years). Treatment included appointments with tinnitus specialists at 3, 6, 12, and 18 months to check the ear-level devices and to receive the group-specific counseling (about 4-5 hours total). At each visit, the subjects completed the THI, Tinnitus Handicap Questionnaire, and Tinnitus Severity Index, and underwent tinnitus and audiologic tests. Questionnaire results showed minor-to-modest improvements at the 3- and 6-month follow-ups for both treatment groups, slightly favoring the masking condition. After 12 months of treatment, medium ESs (0.57-0.66) were reported for the tinnitus retraining group and, after 18 months of treatment, major ESs (0.77-1.26) were obtained. Several confounding variables were reported, including differences in counseling between the 2 groups. This 2006 trial is the only trial that met selection criteria for a 2010 Cochrane review and a systematic review by Grewal et al (2014).

Heidelberg Neuromusic Therapy

Argstatter et al (2015) reported on a 2-center, investigator-blinded RCT with 290 patients treated with neuromusic therapy or a single counseling session. Therapy was provided in eight sessions, 50-minutes each, with 2 sessions a day. Each session consisted of 25 minutes of receptive (music-listening based) and 25 minutes of active (music-making) therapy. Active music therapy included resonance training and intonation training. The receptive music component offered coping mechanisms related to stress control along with a sound-based habituation procedure. Patients in both groups received a 50-minute individualized counseling session. The primary outcome was the change in TQ scores by intention-to-treat analysis at the conclusion of the therapy. Baseline TQ scores were similar in both groups (31.5 points for music therapy vs 31.0 points for counseling). Both groups improved over time, with a greater reduction in TQ scores for music therapy (median, 11.2 points vs 2.3 points). Clinically significant improvements were obtained in 66% of music therapy patients compared with 33% of patients in the active control group.

Multidisciplinary Therapy

Cima et al (2012) reported on a large RCT of usual care vs a combination of approaches. Of the 741 untreated patients who were screened, 247 were assigned to usual care (eg, hearing aids and up to 9 sessions with a social worker) and 245 were assigned to a specialized care protocol. Specialized care included 105 minutes of audiologic diagnostics, 30 minutes of audiologic rehabilitation (hearing aid or masking device), 120 minutes of CBT education, 60 minutes of intake psychology, 40 minutes of audiologic follow-up, and 24 hours of group behavioral and cognitive therapies. About a third of the patients in each group were lost to follow-up at 12 months. Compared with usual care, at 12 months, specialized care resulted in a modest improvement in health-related QOL (ES=0.24), decrease in tinnitus severity (ES=0.43), and decrease in tinnitus impairment (ES=0.45).

Section Summary: Combined Psychological and Sound Therapy

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 (THI

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score) when tinnitus retraining therapy is compared with active or sham controls. For Heidelberg neuromusic therapy, there is a study that used an investigator-blinded RCT design and showed positive short-term results following treatment. The durability of treatment is also unknown. A multidisciplinary therapy was shown to improve outcomes in a large RCT, but because the specialized care protocol was an intensive, multidisciplinary intervention, it is uncertain which of its components were associated with improvements in outcomes. It is also uncertain whether such an intensive treatment could be provided outside of the investigational setting.

REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION

Soleimani et al (2016) published a systematic review of 15 double-blind, randomized trials with sham controls on repetitive transcranial magnetic stimulation (rTMS). Seven of these trials were included in a meta-analysis. The primary outcomes were the mean THI and TQ scores. The secondary outcomes of therapeutic success were defined as a reduction of 7 points on the THI (maximum, 100) or 5 points on the TQ (maximum, 84), but the percentage of patients who achieved therapeutic success was not reported. Mean difference in TQ scores at 1 week after treatment was 3.42 (4 studies). Mean difference in THI scores between the TMS and sham groups was 6.71 at 1 month after treatment (4 studies, $p < 0.001$) and 12.89 at 6 months after treatment (3 studies, $p < 0.001$). The odds ratio at 1 month after treatment was 15.75 ($p = 0.004$), although the sample size was small in the 3 included studies (range, 8-20 patients). A qualitative review of the 15 trials found significant benefit of rTMS in 9 and no significant effect in 6. There was significant heterogeneity in the population, target brain area, stimulation parameters, and length of follow-up.

The largest study included in the 2016 systematic review is that by Langguth et al (2014). It combined data from 2 trials, in which 192 tinnitus patients were randomized to 1 of 3 different rTMS target areas or sham rTMS. The target areas were positron emission tomography-based neuro-navigated rTMS ($n = 48$), rTMS over the left auditory cortex ($n = 48$), or rTMS over both the left auditory cortex and left frontal cortex ($n = 48$). The sham group ($n = 48$) ran concurrently with the navigated rTMS group (between 2004 and 2006) while the other 2 groups ran concurrently between 2007 and 2009. There were no significant differences in mean TQ scores between groups, and no significant differences between groups in improvements in TQ scores over time. The percentage of treatment responders was significantly higher for left temporal rTMS (38%) and combined frontal and temporal rTMS (43%) compared with sham (6%). However, interpretation of these results is limited by the nonconcurrent sham controls.

Folmer et al (2015) published results from a double-blind, sham-controlled randomized trial with 70 patients. Patients received 10 days of rTMS and had follow-up assessments at 1, 2, 4, 13, and 26 weeks after the last treatment session. Sixty-four patients were included in data analysis. Primary outcomes were change from baseline as measured by the TFI score and percentage of responders as measured by a 7-point improvement in TFI score. There were significant differences between groups in change from baseline at weeks 1, 2, and 26, but not at weeks 4 and 13. There was a significantly higher percentage of responders following active rTMS than following sham TMS immediately after treatment (56% vs 22%, $p < 0.005$) and at 26 weeks (66% vs 38%), but not at weeks 1, 4, or 13. The benefit of rTMS increased over the 26 weeks of the trial, with a change in the mean TFI score of -5.2 immediately after treatment, increasing to -13.8 at 26

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weeks. Additional study would be needed to corroborate these results and to evaluate the durability of the treatment.

Section Summary: Repetitive Transcranial Magnetic Stimulation

The evidence on rTMS for tinnitus includes a number of small to moderate-sized randomized, sham-controlled trials and systematic reviews. Results from the trials are mixed, with some not finding a statistically significant effect of rTMS on tinnitus severity. Larger controlled trials for this common condition and longer follow-up are needed to permit conclusions on the effect of this technology on health outcomes.

ELECTRICAL AND ELECTROMAGNETIC STIMULATION

Transcranial Direct Current Stimulation

Song et al (2012) published a systematic review of transcranial direct current stimulation (tDCS) for the treatment of tinnitus. Six studies (3 sham-controlled randomized trials, 3 uncontrolled, open-label studies) were selected for the review. Overall, there was a 39.5% response rate (criteria for responder was not defined), with a mean reduction of tinnitus intensity of 13.5%. Meta-analysis of 2 RCTs showed a medium-to-large ES of 0.77. Pal et al (2015) reported on a trial involving 42 patients randomized to 5 days of sham stimulation or tDCS over the frontal and auditory cortices. They found no beneficial effect of tDCS on the primary (THI score) or secondary outcome measures in this adequately powered double-blind study.

A systematic review by Wang et al (2017) examined the impact of tDCS on patients with tinnitus. Outcomes assessed included: loudness (as observed by a change in magnitude), distress as experienced by those with tinnitus, and THI scores. The results were the following: there was no observable benefit to tDCS in reducing hearing loudness (pooled standardized difference in means, 0.671; 95 CI, -0.089 to 1.437; $p=0.83$); and tinnitus-related distress decreased for those using tDCS (pooled standardized difference in means, 0.634; 95% CI, 0.021 to 1.247; $p=.043$). Only 3 studies dealt with changes in THI scores; however, no statistical heterogeneity could be determined. While this systematic review reported a reduction in tinnitus-related distress, further study is needed to evaluate tDCS as a treatment option for tinnitus.

Direct Current Electrical Stimulation of the Ear

Two randomized trials of transcutaneous electrical stimulation, conducted in the 1980s, reported negative results. Dobie et al (1986) reported on a randomized, double-blind, crossover trial in which 20 patients received an active or disconnected placebo device. Reduction in severity of tinnitus was reported in 2 (10%) of 20 patients with the active device and 4 (20%) of 20 patients with the placebo device. Fifteen (75%) of the 20 patients reported no effect with either device. Thedinger et al (1987) reported on a single-blind crossover trial of 30 patients who received active or placebo stimulation over 2 weeks. Only 2 (7%) of the 30 patients obtained a true positive result.

Mielczarek and Olszewski (2014) reported on a placebo-controlled, nonrandomized trial of DCS of the ear in 120 patients (184 ears) with tinnitus and sensorineural hearing loss. Directly after treatment, tinnitus improved in 37.8% of the active treatment group vs 30.8% of the control group ($p=0.34$). At 90 days, tinnitus had disappeared in 11.8% of patients in the active treatment group compared with 7.7% of controls.

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Electromagnetic Energy

Ghossaini et al (2004) reported on a randomized, double-blind placebo-controlled trial of 37 patients who received placebo or electromagnetic energy treatment with a Diapulse device for 30 minutes, 3 times weekly for 1 month. Trialists found no significant changes in either group in pretreatment and posttreatment audiometric thresholds, THI scores, or tinnitus rating scores, and concluded that pulsed electromagnetic energy (at 27.12 MHz at 600 pulses/s) offered no benefit in the treatment of tinnitus.

Section Summary: Electrical and Electromagnetic Stimulation

The evidence on electrical and electromagnetic stimulation for the treatment of tinnitus includes sham-controlled randomized trials. The available evidence does not currently support the use of these treatments. A 2015 study, sham-controlled and adequately powered, found no benefit of tDCS. Studies have not shown a benefit for DCS of the ear. The evidence on electromagnetic energy includes a small RCT that found no benefit for the treatment of tinnitus.

TRANSMEATAL LASER IRRADIATION

A number of randomized, double-blind placebo-controlled trials have examined transmeatal low-level laser therapy. Most were conducted outside of the United States and showed no efficacy. For example, transmeatal low-level laser was not more effective than placebo in a 2002 double-blind RCT with 60 patients, in a 2009 placebo-controlled, double-blind, randomized trial with 60 patients, a 2014 placebo-controlled, double-blind, randomized trial with 48 patients, or a 2015 placebo-controlled, double-blind, randomized trial with 66 patients.

Section Summary: Transmeatal Laser Irradiation

The evidence on transmeatal laser irradiation includes a number of double-blind RCTs, most of which showed no efficacy of this treatment.

SUMMARY OF EVIDENCE

For individuals who have persistent, bothersome tinnitus who receive psychological coping therapy, the evidence includes 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

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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 (THI 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.

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

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09/18/2002 Managed Care Advisory Council approval

10/05/2004 Medical Director review

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11/16/2004 Medical Policy Committee review
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

11/18/2009 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

11/04/2010 Medical Policy Committee review

11/16/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

11/03/2011 Medical Policy Committee review

11/16/2011 Medical Policy Implementation Committee approval. New investigational indications added.

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

11/21/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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.

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."

Next Scheduled Review Date: 04/2019

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Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 04/18/2018

Coding

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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 | 97014, 97026, 97032 |
| HCPCS | C1816, C1883, E0720, E0761, S8948 |
| ICD-10 Diagnosis | H93.11-H93.19, H93.A1-H93.A9 |

*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. 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;

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- 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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