Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 04/19/2017

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 for persistent and bothersome tinnitus, when self-help or internet-based coping therapies were not effective, to be eligible for coverage.

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 tinnitus maskers, customized sound therapy, combined psychological and sound therapy (e.g., tinnitus retraining therapy) transcranial magnetic stimulation (TMS), transcranial direct current stimulation, electrical transcutaneous electrical stimulation of the ear, transmeatal laser irradiation, and electromagnetic energy, to be investigational.*

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
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.

Tinnitus describes the perception of any sound in the ear in the absence of an external stimulus and presents 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; the latter describes the minority of cases in which an external stimulus is potentially heard by an observer, for example 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. In the majority of cases, tinnitus is subjective and 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.

*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.
Many treatments are supportive in nature, as currently, there is no cure. One treatment, called tinnitus masking therapy, has focused on use of devices worn in the ear that produce a broad band of continuous external noise that dows 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 a researcher named 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 set at a level such that the tinnitus can still be detected. This strategy is thought to enhance extinction of the subconscious 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 that is 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, Neuromonics, Australia) 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 where 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 that is being investigated utilizes music with the frequency of the tinnitus removed (notched music) to promote reorganization of sound processing in the auditory cortex. One theory behind 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 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. Transmeatal low-power laser irradiation, electrical stimulation and transcranial magnetic stimulation 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 that has been cleared for marketing by the 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: K LW.
Centers for Medicare and Medicaid Services (CMS)
The Centers for Medicare and Medicaid Services had a longstanding national coverage determination (NCD) for tinnitus masking, which was considered an experimental therapy because of the lack of controlled clinical trials demonstrating effectiveness and the unstudied possibility of serious toxicity in the form of noise-induced hearing loss. The NCD was retired in 2014.

Rationale/Source
Since tinnitus is a subjective symptom without a known physiologic explanation, randomized placebo-controlled trials are particularly important to validate the effectiveness of any treatment compared to the expected placebo effect.

In 2013, the Agency for Healthcare Research and Quality published a comparative effectiveness review on the evaluation and treatment of tinnitus. Treatments evaluated included laser, TMS, 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 were included on medical interventions, 4 on sound technology interventions, and 19 on psychological and behavioral interventions. The review found insufficient evidence for medical and sound technology interventions. For psychological and behavioral interventions, there was low evidence of an effect for cognitive behavioral therapy (CBT) on tinnitus-specific quality of life, and low evidence of no effect for CBT on subjective loudness, sleep disturbance, anxiety, depression, and global quality of life (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 presence of symptoms for at least 6 months and subjective impairment or annoyance. The experimental groups included CBT, self-help CBT, tinnitus coping therapy (TCT), 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. RCTs Included in the Meta-Analysis by Martinez-Devesa et al (2010)

<table>
<thead>
<tr>
<th>Study</th>
<th>Groups</th>
<th>N</th>
<th>Inclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andersson et al (2005)</td>
<td>CBT, waitlist</td>
<td>23</td>
<td>≥17 points on TRQ</td>
</tr>
<tr>
<td>Henry et al (1996)</td>
<td>CBT, education, waitlist</td>
<td>60</td>
<td>≥17 points on TRQ</td>
</tr>
<tr>
<td>Kaldor et al (2007)</td>
<td>Self-help CBT, waitlist</td>
<td>72</td>
<td>≥10 points on TRQ</td>
</tr>
<tr>
<td>Kroner-Herwig et al (1995)</td>
<td>CBT, yoga, waitlist</td>
<td>43</td>
<td>&gt;4 of 10-point scale for impairment</td>
</tr>
<tr>
<td>Kroner-Herwig et al (2003)</td>
<td>TCT, education, relaxation,</td>
<td>95</td>
<td>&gt;40 of 100-point scale for annoyance</td>
</tr>
<tr>
<td>Rief et al (2005)</td>
<td>Psychophysiological, waitlist</td>
<td>43</td>
<td>&gt;3 of 10-point scale for annoyance</td>
</tr>
<tr>
<td>Weise et al (2008)</td>
<td>Biofeedback, waitlist</td>
<td>111</td>
<td>≥47 points on TQ</td>
</tr>
</tbody>
</table>
Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 04/19/2017

CBT: cognitive-behavioral therapy; RCT: randomized controlled trial; TCT: tinnitus coping therapy; TRQ: Tinnitus Reaction Questionnaire; TQ: Tinnitus Questionnaire.

Cognitive Behavioral Therapy

In 2013, Zenner et al reported a multicenter pragmatic trial of a standardized individual tinnitus-specific CBT program versus 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 control group. There were differences between the groups at baseline for tinnitus compensation, tinnitus quality, and tinnitus duration. In addition, 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 an efficacy of treatment with an odds ratio (OR) of 3.4 (95% confidence interval [CI], 2.6 to 4.5) in intention-to-treat analysis. Improvement in the tinnitus change score with a score of 2 or better was reported in 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 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

In 2011, Westin et al. reported a randomized controlled trial (RCT) of acceptance and commitment therapy (ACT) versus tinnitus retraining therapy or waiting-list control in 64 normal hearing patients. The ACT treatment consisted of 10 weekly 60 min sessions, and the tinnitus retraining therapy consisted of one 150 min session, one 30 min 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 improved from 45.27 at baseline to 28.19 at 18 months. In the tinnitus retraining group, THI improved from 47.00 at baseline to 41.86 at 18 months, while the waiting-list control was unchanged at 48.29. The THI was 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

A 2007 RCT by Kaldo et al. found that a CBT self-help book for tinnitus combined with 7 weekly phone calls from a therapist reduced distress (greater than 50% on the tinnitus reaction questionnaire) in 32% of subjects compared with 5% of the waiting-list control group. 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, since 26% to 28% of patients from both groups showed distress reduction at 1 year. A subsequent RCT by Kaldo and colleagues found that an Internet-based self-help program was as effective as standardized group-based cognitive-behavior therapy for reducing tinnitus distress.

These RCTs were followed by a 2012 RCT of internet-delivered 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) format 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 to 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.

A 2014 RCT by Jasper et al 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 (n=44).11 Both CBT interventions resulted in significant improvements in the primary outcome measures of the THI and Mini-Tinnitus Questionnaire, 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, responder rate was 49% for ICBT and 51% for GCBT. Responder analysis was not reported for the control group. The amount of time that therapists spent for each patient was similar for the 2 groups, with an average of 11 messages sent and 9 received in the ICBT group and an average of 10 participants in each 90-minute 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 to a moderated online discussion forum. For the primary outcome of tinnitus-related distress, there was a significant interaction of time by group that was supported by large effect sizes (THI standardized effect size [SES], 0.83; 95% CI, 0.47 to 1.20; TQ SES=1.08; 95% CI, 0.71 to 1.64). For the secondary outcomes, Hospital Anxiety and Depression Scale (HADS), Tinnitus Acceptance Questionnaire, and Insomnia Severity Index, small-to-medium effect sizes 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.

Section Summary: Psychological Coping Therapy
The evidence for 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 quality of life. Meta-analyses of a variety of cognitive and behavioral therapies have found improvement in global tinnitus severity and QOL, even when tinnitus loudness is 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 Therapies
Tinnitus Masking
A 2010 Cochrane review, with an update in 2012, evaluated the evidence for masking in the management of tinnitus in adults. Included in the review 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. The authors 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 study of preferences for hearing aids and tinnitus maskers in 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 have been identified on a variety of methods of customized sound therapy. These studies are divided by the type of sound therapy.

**Neuromonics Tinnitus Treatment**

An 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/exclusion criteria. The mean length of time that their tinnitus had been disturbing was 3.6 years (range 0.2 to 23). Patients were allocated into 1 of 4 groups, 1) customized acoustic stimulus at high intensity for 2 hours per 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 per 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; use of the devices averaged 1.8 hours per day (range 0.4 to 6.8). 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 the groups). All patients lost to follow-up were included in the dataset for analysis with a “last value carried forward.” Mean scores on the Tinnitus Reaction Questionnaire (TRQ) improved over the 12 months of the study for the customized acoustic stimuli. Tinnitus Reaction Questionnaire scores were not significantly improved in the control groups. At the 6-month follow-up, 86% of patients in the customized acoustic stimuli groups had met the definition of success based on 40% improvement in TRQ scores. Normalized visual analogue scores (VAS) 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 device described results for the first 552 patients who had treatment at specialized clinics in Australia. Patients were divided into 3 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 less than 17) and/or moderately severe or severe hearing loss in one ear (greater than 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, multi-tone tinnitus, pulsatile tinnitus, Meniere’s disease, and/or hearing loss of greater than 50 decibels (dBs) in both ears. Of the 552 patients who began therapy, 62 (11%) chose to discontinue treatment for refund and 20 (4%) were lost to follow-up. After an average treatment duration of 37 weeks,
Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 04/19/2017

the TRQ was reported to be improved (by greater than 40%) in 92% of tier 1 patients, 60% of tier 2 patients, and 39% of tier 3 patients. It was not reported if the reduction in symptoms persisted when treatment stopped. Controlled studies with long-term follow-up are needed to evaluate the durability of treatment and the relative contribution of generalized masking versus desensitization to these results.

Auditory Discrimination Training
Herraiz et al (2010) randomized 45 patients scoring mild or moderate on the THI: (less than 56) to auditory discrimination training with the same frequency as the tinnitus pitch (SAME) or training on a frequency near to but not the same as the tinnitus pitch (NONSAME). An additional 26 patients were included in a waiting-list control group. The 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. A total of 41 (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 with 42% of patients in the auditory discrimination training group. Subjective improvement in tinnitus intensity was modest and similar in the 2 groups (0.65 vs 0.32, respectively). The decrease in THI scores was significantly greater in the patients with NONSAME frequencies (11.31) than patients trained on SAME frequencies (2.11, p=0.035).

Notched Music
In another publication from 2010, Okamato et al. reported a small (n=24) double-blinded pseudo-randomized trial that compared 12 months of listening to notched music (the tinnitus frequency was removed) or placebo music. An additional group of patients who were not able to participate in the music training due to time constraints served as a monitoring control. Thirty-nine patients who met the strict study inclusion criteria were recruited; the final group sizes after dropouts and exclusions was 8 in the target-notched music group, 8 in the placebo group, and 7 in the monitoring group. After 12 months of music (approximately 12 hours per week), there was a significant decrease in tinnitus loudness (about 30%) in the target group but not in the placebo or monitoring groups. Evoked activity to the tinnitus frequency, measured by magnetoencephalography (MEG), was also reduced in the primary auditory cortex of the target group but not in the placebo or monitoring groups. The change in subjective tinnitus loudness and auditory-evoked response ratio were 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 subjects are needed to evaluate this novel and practical treatment approach.

In 2016, Stein et al 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 VAS scores and tinnitus distress on the THQ. No effect was found for the primary outcome measures by either ITT or per protocol analysis, although the subscale of tinnitus loudness was reported to be reduced.
Sound Options Tinnitus Treatments
In 2016, Li et al 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 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, 4 dropped out during follow-up, and 9 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 score and treatment adherence, was -17.41 on the THI (p=0.001), with an effect size 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 treated group but remained unchanged (at 63%) in the control group. Scores did not differ significantly between groups for Tinnitus Functional Index (TFI) or HADS scores. Interpretation of this study is 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 medium-to-high risk of bias, 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 subcomponent 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 using tinnitus retraining therapy. One trial did not find an improvement over an education-only intervention, and 2 provided low-quality evidence for the efficacy of an individualized multicomponent intervention that included tinnitus retraining. Additional controlled studies are described next.

The 2011 RCT by Westin et al (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 over the course of 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 was unchanged at 48.29. Interpretation of these findings is limited by the lack of a placebo-control group.
In 2011, Bauer and Brozoski 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.

Another pseudorandomized trial from a Veterans Administration medical center, published in 2006, compared tinnitus masking and 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 improvement at the 3- and 6-month follow-ups for both treatment groups, favoring slightly the masking condition. After 12 months of treatment, medium effect sizes (0.57-0.66) were reached for the tinnitus retraining group and, after 18 months of treatment, major effect sizes (0.77-1.26) were obtained. It was noted by the authors that several confounding variables were present in this study, including differences in counseling between the 2 groups. The 2006 trial is the only trial that met selection criteria for a 2010 Cochrane review and a 2014 systematic review by Grewal et al.

Heidelberg Neuron-Music Therapy
In 2015, Argstatter et al reported a 2-center, investigator-blinded RCT with 290 patients who were treated with either neuromusic therapy or a single counseling session. Therapy was provided in eight 50-minute sessions, with 2 sessions per 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 the TQ by intention-to-treat analysis at the conclusion of the therapy. Baseline TQ scores were similar in the 2 groups (31.5 points for music therapy vs 31.0 points for the counseling control group). Both groups improved over time, with a greater reduction in the TQ 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
In 2012, Cima et al reported a large RCT of usual care versus a combination of approaches. Of 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 audiological diagnostics, 30 minutes of audiological rehabilitation (hearing aid or masking device), 120 minutes of CBT education, 60 minutes of intake psychology, 40 minutes of audiological 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 quality of life (effect size [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-randomized controlled trials. Together, the literature does not show consistent improvement in the primary outcome measure (THI score) when tinnitus retraining therapy is compared with active or sham controls. For Heidelberg neuromusic therapy there is 1 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
In 2016, Soleimani et al published a systematic review of 15 double-blind randomized trials with sham controls on 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 OR 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). The qualitative review of the 15 trials found significant benefit of repetitive transcranial magnetic stimulation (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 was 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 to sham rTMS. The target areas were positron emission tomography–based neuronavigated 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 difference between groups in the improvement 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 to sham (6%). However, interpretation of these results is limited by the nonconcurrent sham controls.

In 2015, Folmer et al published results from a double-blind sham-controlled RCT 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 and percentage of responders measured by a 7-point improvement in the TFI. There was a significant difference between groups in change from baseline at weeks 2, 4, and 26, but not at weeks 1, 4, and 13. There was a significantly higher percentage of responders following active rTMS compared to 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 study, with a change in the mean TFI score of -5.2 immediately after treatment, increasing to -13.8 at 26 weeks. Additional study is needed to corroborate these results and to evaluate the durability of the treatment.

Section Summary: 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 studies are mixed, with some trials 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 regarding the effect of this technology on health outcomes.

Electrical Stimulation of the Ear
Transcranial Direct Current Stimulation
In 2012, Song et al published a systematic review of transcranial direct current stimulation (tDCS) for the treatment of tinnitus. Six studies (3 sham-controlled RCTs, 3 uncontrolled, open-label studies) were included in 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 of the RCTs showed a medium to large effect size of 0.77. In 2015, Pal et al reported 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) or secondary outcome measures in this adequately powered double-blind study.

Direct Current Electrical Stimulation of the Ear
Two randomized trials of transcutaneous electrical stimulation were reported in the 1980s with 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. Theodinger 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.
In 2014, Mielczarek and Olszewski reported a placebo-controlled, nonrandomized trial of direct current stimulation 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 versus 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.

**Electromagnetic Energy**

Ghossaini et al (2004) reported on a randomized, double-blind placebo-controlled RCT of 37 patients who received either placebo treatment or electromagnetic energy treatment with a Diapulse device for 30 minutes, 3 times weekly for 1 month. The authors 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 use of these treatments. A 2015 study, sham-controlled and adequately powered, found no benefit of tDCS. Studies have not shown a benefit for direct current electrical stimulation 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 double-blind RCT with 60 patients from 2002, 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.

**Ongoing and Unpublished Clinical Trials**

Some ongoing trials that might influence this policy are listed in Table 1.

**Table 2. 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>NCT02293512</td>
<td>A Comparison of CBT and CET Interventions for Veterans With Tinnitus</td>
<td>80</td>
<td>Nov 2016 (ongoing)</td>
</tr>
<tr>
<td>NCT01177137</td>
<td>Tinnitus Retraining Therapy Trial</td>
<td>228</td>
<td>Feb 2017</td>
</tr>
<tr>
<td>NCT02370810</td>
<td>Study Protocol for a CBT-based Internet Intervention for Adults</td>
<td>160</td>
<td>Mar 2017</td>
</tr>
</tbody>
</table>
Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 04/19/2017

<table>
<thead>
<tr>
<th>Trial ID</th>
<th>Title</th>
<th>Study Type</th>
<th>NCT ID</th>
<th>Enrollment</th>
<th>Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT02665975</td>
<td>Internet-based Versus Face-to-face Clinical Care for Tinnitus: A Multi-study Randomised Control Trial</td>
<td>RCT</td>
<td>80</td>
<td>Jul 2017</td>
<td></td>
</tr>
<tr>
<td>NCT02653547</td>
<td>Influence of Treatment Duration and Stimulation Frequency on Repetitive Transcranial Magnetic Stimulation in Chronic Tinnitus</td>
<td>RCT</td>
<td>80</td>
<td>Jul 2017</td>
<td></td>
</tr>
<tr>
<td>NCT02438891</td>
<td>Evaluation of an Internet-based Sound and Cognitive Behavioral Therapy Course for Treatment for Tinnitus</td>
<td>RCT</td>
<td>200</td>
<td>Jul 2018</td>
<td></td>
</tr>
</tbody>
</table>

Unpublished

<table>
<thead>
<tr>
<th>Trial ID</th>
<th>Title</th>
<th>Study Type</th>
<th>NCT ID</th>
<th>Enrollment</th>
<th>Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01929837</td>
<td>Treatment of Tinnitus With Transcranial Magnetic Stimulation</td>
<td>RCT</td>
<td>80</td>
<td>Aug 2016 (completed)</td>
<td></td>
</tr>
<tr>
<td>NCT02408575</td>
<td>Hearing Aids With &quot;Notched Amplification&quot; for the Treatment of Chronic Tinnitus - A Controlled Randomized Pilot Study on Safety, Tolerability and Clinical Performance</td>
<td>RCT</td>
<td>44</td>
<td>Jun 2016 (completed)</td>
<td></td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

Summary

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 improvement 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 have medium-to-high risk of bias and did not show efficacy of masking therapy. Research on customized sound therapy appears to be at an early stage. For example, the studies described 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 (eg, tinnitus retraining 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-randomized controlled trials. Together, the literature does not show a consistent improvement in the primary outcome measure (Tinnitus Handicap Inventory) when tinnitus retraining therapy is compared with active or sham controls. For Heidelberg neuromusic therapy, 1 trial has...
Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 04/19/2017

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 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The available evidence does not currently support use of these treatments. A 2015 sham-controlled study that was adequately powered found no benefit of transcranial direct current stimulation. 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 double-blind RCTs, most of which showed no efficacy of this treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

References
Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 04/19/2017


©2017 Blue Cross and Blue Shield of Louisiana
An independent licensee of the Blue Cross and Blue Shield Association
No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 04/19/2017


Policy History
Original Effective Date: 09/18/2002
Current Effective Date: 04/19/2017
09/11/2002 Medical Director review
09/18/2002 Managed Care Advisory Council approval
10/04/2004 Medical Director review
11/16/2004 Medical Policy Committee review
11/29/2004 Managed Care Advisory Council approval.
07/07/2006 Format revision. Policy amended to include transmeatal irradiation as investigational.
11/14/2006 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.
11/12/2009 Medical Policy Committee approval
11/18/2009 Medical Policy Implementation Committee approval.
11/04/2010 Medical Policy Committee review
11/16/2010 Medical Policy Implementation Committee approval.
11/03/2011 Medical Policy Committee review
11/16/2011 Medical Policy Implementation Committee approval.
11/01/2012 Medical Policy Committee review
11/28/2012 Medical Policy Implementation Committee approval.
11/07/2013 Medical Policy Committee review
11/20/2013 Medical Policy Implementation Committee approval.
11/06/2014 Medical Policy Committee review
11/21/2014 Medical Policy Implementation Committee approval.
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.
11/03/2016 Medical Policy Committee review

©2017 Blue Cross and Blue Shield of Louisiana
An independent licensee of the Blue Cross and Blue Shield Association
No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 04/19/2017

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.

Next Scheduled Review Date: 04/2018

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 2016 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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

CPT is a registered trademark of the American Medical Association.

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>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>96152, 92625, 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. 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
Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 04/19/2017

3. Reference to federal regulations.

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

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

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

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

NOTICE: 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.