

# Medical Policy



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## Title: Treatment of Tinnitus

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Populations	Interventions	Comparators	Outcomes
Individuals: • With tinnitus	Interventions of interest are: • Cognitive and behavioral coping therapies	Comparators of interest are: • Observation • Pharmacologic management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With tinnitus	Interventions of interest are: • Sound therapy	Comparators of interest are: • Observation • Pharmacologic management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With tinnitus	Interventions of interest are: • Repetitive transcranial magnetic stimulation	Comparators of interest are: • Observation • Pharmacologic management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With tinnitus	Interventions of interest are: • Transcranial direct current stimulation • Electrical stimulation of the ear	Comparators of interest are: • Observation • Pharmacologic management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With tinnitus	Interventions of interest are: • Transmeatal laser irradiation • Electromagnetic energy	Comparators of interest are: • Observation • Pharmacologic management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With tinnitus	Interventions of interest are: • Botulinum toxin type A	Comparators of interest are: • Observation • Pharmacologic management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

## **DESCRIPTION**

Various nonpharmacologic treatments are being evaluated to improve the subjective symptoms of tinnitus. These approaches include cognitive and behavioral therapies, use of tinnitus maskers, tinnitus-retraining therapy, customized sound therapy, transcranial magnetic stimulation, transcranial direct current stimulation, electrical stimulation of the ear, transmeatal laser irradiation, electromagnetic energy, and botulinum toxin A injections.

## **Background**

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 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. 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.

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 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 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.

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 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 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. 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.

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, electromagnetic energy, transcranial magnetic stimulation, and botulinum toxin A injections have also been evaluated.

### **Regulatory Status**

The Neuromonics® Tinnitus Treatment is one of many tinnitus maskers that has been cleared for marketing by the U.S. Food and Drug Administration (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.

## **POLICY**

Treatment of tinnitus is considered **experimental / investigational** with any of the following:

1. tinnitus coping therapy
2. tinnitus maskers
3. tinnitus-retraining therapy
4. customized sound therapy
5. transcranial magnetic stimulation
6. transcranial direct current stimulation
7. electrical transcutaneous electrical stimulation of the ear
8. transmeatal laser irradiation
9. electromagnetic energy
10. botulinum toxin type A injections

## **RATIONALE**

This evidence review has been updated using the MEDLINE database. The most recent review was performed through December 10, 2015.

Because 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 with 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.<sup>1</sup> Treatments evaluated included laser, transcranial magnetic stimulation (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 for an effect of cognitive-behavioral therapy (CBT) on tinnitus-specific quality of life, and low evidence for no effect of CBT on subjective loudness, sleep disturbance, anxiety, depression, and global quality of life. Evidence was insufficient for other psychological and behavioral interventions such as tinnitus retraining therapy and relaxation.

### **Coping Therapy (Cognitive and Behavioral)**

In 2012, Cima et al reported a large randomized controlled trial (RCT) of usual care versus a combination of cognitive and behavioral approaches.<sup>2</sup> 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 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 quality of life (effect size, 0.24), decrease in tinnitus severity (effect size, 0.43), and decrease in tinnitus impairment (effect size, 0.45). Because the specialized care protocol was an intensive, multidisciplinary intervention, it is uncertain which of its components were associated with improvements in outcomes and whether such an intensive treatment could be provided outside of the investigational setting.

### **Cognitive-Behavioral Therapy**

A 2007 Cochrane review identified 6 RCTs in which 285 patients with tinnitus received CBT or a control condition (another treatment or waiting list).<sup>3</sup> Analysis found no significant effect in the subjective loudness of tinnitus or in associated depression. However, a significant improvement in quality of life (ie, decrease of global tinnitus severity) was found, suggesting that CBT has a positive effect on the way in which people cope with tinnitus. This Cochrane review was updated in 2010 with 2 additional trials and a total of 468 participants.<sup>4</sup> As was previously found, there was no significant difference in subjective tinnitus loudness with CBT and either no treatment or another intervention, but there was an improvement in quality of life associated with decreased global tinnitus severity. The updated 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). No additional RCTs were identified in a 2014 systematic review of the literature.<sup>5</sup>

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.<sup>6</sup> Four sites enrolled patients into the CBT program, while a fifth site enrolled patients into the waiting-list 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 treatment efficacy 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 by 2 or more points 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 versus 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. Interpretation of this trial is limited by the potential for bias in these subjective measures.

### **Acceptance and Commitment Therapy**

In 2011, Westin et al reported an RCT of acceptance and commitment therapy (ACT) versus tinnitus retraining therapy or waiting-list control in 64 patients with normal hearing.<sup>7</sup> The ACT group (n=22) received treatment 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 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 ( $\geq 50\%$  on the Tinnitus Reaction Questionnaire [TRQ]) in 32% of 34 subjects compared with 5% of 38 waiting-list controls.<sup>8</sup> 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 found that an Internet-based self-help program was as effective as standardized group-based CBT for reducing tinnitus distress.<sup>9</sup>

These RCTs were followed by a 2012 RCT of Internet-based CBT or ACT.<sup>10</sup> 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.

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 that represented the control condition ( $n=44$ ).<sup>11</sup> 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, the 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 between 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 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.

### **Section Summary: Tinnitus Coping Therapy (Cognitive and Behavioral)**

The literature indicates that psychological therapies do not improve tinnitus loudness but can improve coping skills and quality of life when compared with waiting-list controls. There is some evidence that self-help and Internet-based therapies may be as effective as traditional group therapy for ACT and CBT, although patients in 1 study expressed greater satisfaction with group treatment.

## **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.<sup>12,13</sup> 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.<sup>14</sup>

### **Tinnitus Retraining Therapy**

A 2011 systematic review identified 3 RCTs using tinnitus retraining therapy.<sup>15</sup> One study 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) reported results of tinnitus retraining compared with ACT or waiting-list control in 64 patients with normal hearing.<sup>7</sup> In this trial, tinnitus retraining was significantly less effective than ACT. The percent of patients with reliable improvement 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, the THI improved from 47.00 at baseline to 41.86 at 18 months, while the waiting-list control 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 a pseudorandomized study of tinnitus retraining therapy in 32 patients with normal to near-normal hearing (75% follow-up).<sup>16</sup> Group assignment was balanced by tinnitus severity on the THI, Beck Depression Inventory scores, and sex. Participants were assigned to 8 hours 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 per 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 the THI. Secondary outcome measures were change in global tinnitus impact, subjective tinnitus loudness rating, and objective tinnitus loudness measured by a psychophysical matching procedure. THI improved over the 18 months of the study 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 was no between-group difference 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.<sup>17</sup> 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-up for both treatment groups, slightly favoring 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.<sup>5,18</sup>

### **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***

A 2008 industry-sponsored randomized study compared treatment with a proprietary customized acoustic stimulus for tinnitus retraining or counseling alone.<sup>19</sup> 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, 0.2-23 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; use of the devices 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 the groups). All patients lost to follow-up were included in the dataset for analysis using "last value carried forward." Mean scores on the TRQ improved for the combined customized acoustic stimuli group over the 12 months of the study. TRQ scores were not significantly improved 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 (VAS) 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 device described results for the first 552 patients who received treatment at specialized clinics in Australia.<sup>20</sup> 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 1 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 1 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%) chose to discontinue treatment for refund, and 20 (4%) were lost to follow-up. After an average treatment duration of 37 weeks, the TRQ was improved (>40%) in 92% of tier 1 patients, 60% of tier 2 patients, and 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 are needed to evaluate the durability of

treatment and the relative contribution to these results of generalized masking versus 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 (SAME) or training on a frequency near to but not the same as the tinnitus pitch (NONSAME).<sup>21</sup> An additional 26 patients were included in a waiting-list control group. Auditory discrimination training 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 in the NONSAME group (54%) compared with the SAME group (26%), although subjective improvement was variable, and the difference was not statistically different. Subjective improvement in VAS 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 2010 publication, Okamoto et al reported a small (N=24) double-blind, pseudorandomized trial that compared 12 months of listening to notched music (with the tinnitus frequency removed) or placebo music.<sup>22</sup> An additional group of patients who were unable 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 ( $\approx 12$  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 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 patients are needed to evaluate this novel and practical treatment approach.

### ***Heidelberg Neuron-Music Therapy***

In 2015, Argstatter et al reported a 2-center, investigator-blinded RCT with 290 patients who were treated with neuromusic therapy or a single counseling session.<sup>23</sup> 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. The study was generally of high methodologic quality. However, as there may have been differing expectations due to differences in intensity of treatment and lack of blinding, there is a high potential for bias. The durability of treatment is also unknown.

### **Section Summary: Sound Therapy**

Sound therapies include tinnitus masking, tinnitus retraining therapy, 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. 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 (THI) when tinnitus retraining therapy is compared with active or sham controls. 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. No studies from the United States were identified.

### **Transcranial Magnetic Stimulation**

In 2015, Soleimani et al published a systematic review of 15 double-blind randomized trials with sham controls.<sup>24</sup> 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 2015 systematic review was by Langguth et al (2014).<sup>25</sup> 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.<sup>26</sup> 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 Tinnitus Functional Index (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 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.<sup>27</sup> 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.<sup>28</sup> 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.<sup>29</sup> 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.<sup>30</sup> 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.<sup>31</sup> Directly after treatment, tinnitus improved in 37.8% of the active treatment group versus 30.8% of the control group ( $\chi^2$  test,  $p = 0.34$ ). At 90 days, tinnitus had disappeared in 11.8% of patients in the active treatment group compared with 7.7% of controls.

## Other Nonpharmacologic Treatments

### Transmeatal Laser Irradiation

A number of randomized double-blind placebo controlled trials have examined transmeatal low-level laser therapy. Most are from outside of the United States and show no efficacy. For example, transmeatal low-level laser was not more effective than placebo in a double-blind RCT with 60 patients from 2002,<sup>32</sup> in a 2009 placebo-controlled, double-blind RCT with 60 patients,<sup>33</sup> a 2014 placebo-controlled, double-blind RCT with 48 patients,<sup>34</sup> and a 2015 placebo-controlled, double-blind RCT with 66 patients.<sup>35</sup>

### 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.<sup>36</sup> 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.

### Botulinum Toxin Type A

Stidham et al (2005) explored the use of botulinum toxin type A injections for tinnitus treatment under the theory that blocking autonomic pathways could reduce the perception of tinnitus.<sup>37</sup> Thirty patients were randomized in a double-blind, crossover trial to receive either 3 subcutaneous injections of botulinum toxin A around the ear followed by placebo injections 4 months later or placebo injections first followed by botulinum toxin A. Only 26 patients completed the trial and were included in data analysis. Seven of 26 patients had reduced tinnitus after the botulinum toxin type A injections, which was statistically significant when compared with the placebo groups in which only 2 patients (8%) reported reduced tinnitus ( $p < 0.005$ ). THI scores were also significantly decreased between pretreatment and 4 months after botulinum toxin type A injections. However, no other significant differences were noted when comparing treatments at 1 and 4 months after injections. Larger studies are needed to evaluate the potential benefits of botulinum toxin type A for the treatment of tinnitus.

### Section Summary: Other Nonpharmacologic Treatments

Other nonpharmacologic treatments include transmeatal laser irradiation, electromagnetic energy, and botulinum toxin type A. The evidence on transmeatal laser irradiation includes a number of double-blind RCTs, most of which show no efficacy of this treatment. The evidence on electromagnetic energy includes a small RCT that found no benefit for the treatment of THI. The evidence on botulinum toxin type A includes a small crossover trial that showed benefit on some outcome measures. Additional study is needed.

### Ongoing and Unpublished Clinical Trials

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

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
NCT02370810	Study Protocol for a CBT-based Internet Intervention for Adults With Tinnitus in the United Kingdom: A Randomised Controlled Trial	80	Nov 2016
NCT02293512	A Comparison of CBT and CET Interventions for Veterans With Tinnitus	80	Dec 2016
NCT02665975	Internet-based Versus Face-to-face Clinical Care for Tinnitus: A Multi-study Randomised Control Trial	80	Jun 2017
NCT02653547	Influence of Treatment Duration and Stimulation Frequency on Repetitive Transcranial Magnetic Stimulation in Chronic Tinnitus	80	Jul 2017
NCT01177137	Tinnitus Retraining Therapy Trial	228	Jun 2018
NCT02438891	Evaluation of an Internet-based Sound and Cognitive Behavioral Therapy Course for Treatment for Tinnitus	200	Jul 2018
<b>Unpublished</b>			
NCT01929837	Treatment of Tinnitus With Transcranial Magnetic Stimulation	80	Dec 2015
NCT02408575	Hearing Aids With "Notched Amplification" for the Treatment of Chronic Tinnitus - A Controlled Randomized Pilot Study on Safety, Tolerability and Clinical Performance	40	Feb 2016

NCT: national clinical trial.

### Summary of Evidence

The evidence for cognitive and behavioral coping therapies in individuals who have tinnitus includes a number of randomized controlled trials (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. One large, well-conducted RCT using an intensive, multidisciplinary intervention showed improvement in outcomes, but generalizability is a concern because it is uncertain whether the intensive treatment approach used could be replicated outside the investigational setting. Another RCT reported that a self-help/Internet-based approach to cognitive and behavioral therapy or acceptance and commitment therapy may also improve coping skills. Additional studies are needed to determine the efficacy of this treatment modality and the most effective method of delivering psychological coping therapy outside of the investigational setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for sound therapies in individuals who have tinnitus 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 a number of RCTs and a systematic review of RCTs. The RCTs have medium-to-high risk of bias and do not show efficacy of masking 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 a consistent improvement in the primary outcome measure (Tinnitus Handicap Inventory [THI])

when tinnitus retraining therapy is compared with active or sham controls. Research on customized sound therapy 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. No studies from the United States were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for transcranial magnetic stimulation in individuals who have tinnitus 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.

The evidence for transcranial direct current stimulation and direct current electrical stimulation of the ear in individuals who have tinnitus includes a number of small RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Evidence includes a number of small RCTs, many of which report no benefit of these treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for transmeatal laser irradiation, electromagnetic energy, and botulinum toxin type A 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 on electromagnetic energy includes a small RCT that found no benefit for the treatment of tinnitus. The evidence for botulinum toxin type A includes a small crossover trial that showed benefit on some outcome measures. Additional study is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **Practice Guidelines and Position Statements**

In 2014 the American Academy of Otolaryngology–Head and Neck Surgeons published evidence-based guidelines on tinnitus. The guidelines include the following recommendations<sup>38</sup>:

- Clinicians should differentiate between bothersome and non-bothersome tinnitus. (Strong recommendation based on Grade B evidence of inclusion criteria for RCTs on tinnitus treatment, with a preponderance of benefit over harm.)
- Clinicians should distinguish patients with bothersome tinnitus of recent onset from those with persistent symptoms ( $\geq 6$  months) to prioritize intervention and facilitate discussion about natural history and follow-up care. (Recommendation based on Grade B evidence of inclusion criteria for RCTs on tinnitus treatment, with a preponderance of benefit over harm.)
- Clinicians should educate patients with persistent, bothersome tinnitus about management strategies. (Recommendation based on grade B evidence from studies of the value of education and counseling in general, and grade C evidence based on such studies in tinnitus in particular, with a preponderance of benefit over harm.)
- Clinicians may recommend sound therapy to patients with persistent, bothersome tinnitus. (Option, based on grade B evidence of RCTs with methodological concerns.)

- Clinicians should recommend cognitive behavioral therapy (CBT) to patients with persistent, bothersome tinnitus. (Recommendation based on grade A evidence from multiple systematic reviews of RCTs.)
- Clinicians should not recommend antidepressants, anticonvulsants, anxiolytics, or intratympanic medications for a primary indication of treating persistent, bothersome tinnitus. (Recommendation [against] based on grade B evidence from RCTs with methodological and systematic reviews demonstrating a low strength of evidence.)
- Clinicians should not recommend transcranial magnetic stimulation (TMS) for the treatment of patients with persistent, bothersome tinnitus. (Recommendation [against] based on inconclusive RCTs and systematic reviews that show low strength of evidence.)

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### CODING

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

#### CPT/HCPCS

92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97026	Application of a modality to 1 or more areas; infrared
E0720	Transcutaneous electrical nerve stimulation (TENS) device, 2 lead, localized stimulation
E1399	Durable medical equipment, miscellaneous
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes

- There are no specific CPT codes for electrical stimulation or tinnitus-retraining therapy. The CPT codes used may include evaluation and management CPT codes or possibly the physical medicine and rehabilitation code (97014) or speech therapy (92507). As tinnitus-retraining therapy in part involves counseling, an individual psychotherapy CPT code may be used (code range 90832-90838). Tinnitus-retraining therapy may also be billed as physical or speech therapy.
- There is no specific CPT code for low-level laser therapy. However, providers may elect to use CPT code 97026 because the laser emits light in the infrared spectrum. In January 2004, a HCPCS code (S8948) was added that is specific to low-level laser therapy.
- As described in the literature, electrical stimulation is an office-based procedure, but if self-administered by the patient, the device could possibly be described by HCPCS code E0720.
- Tinnitus-masking devices represent a piece of durable medical equipment. There is currently no specific HCPCS code describing these devices.
- There is a specific CPT code for tinnitus assessment – 92625: Assessment of tinnitus (includes pitch, loudness matching, and masking).

**DIAGNOSES**

Experimental / Investigational for all diagnoses related to this medical policy.

**REVISIONS**

06-30-2009	Policy added to the bcbsks.com web site. No policy changes were made.
08-30-2012	Description section updated
	In Policy section: <ul style="list-style-type: none"> <li>▪ Added the following experimental / investigational treatments to the policy: tinnitus coping therapy, transcutaneous electrical stimulation, sound therapy</li> </ul>
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> <li>▪ Added the following CPT / HCPCS codes: 92507, 92625, 97014, E0720, S8948</li> </ul>
	References updated
01-15-2013	In the Coding section: <ul style="list-style-type: none"> <li>▪ In bullet #1, removed "90804-90809" and inserted "90832-90838" (Effective 12-31-2012)</li> </ul>
11-12-2013	Description section updated
	Rationale section updated
	In Coding section <ul style="list-style-type: none"> <li>▪ Correction: CPT Code 92625 was not added to the medical policy as noted in the 08-30-2012 Revision update. This code pertains to assessment of tinnitus and the policy pertains to treatment.</li> </ul>
	References updated
11-24-2015	Description section updated
	Rationale section updated
	References updated
08-04-2016	Description section updated.
	In Policy section: <ul style="list-style-type: none"> <li>▪ In Item 4 added "customized" to read customized sound therapy"</li> <li>▪ Added Item 6 "transcranial direct current stimulation"</li> <li>▪ In Item 7 added "electrical" and "of the ear" to read "electrical transcutaneous electrical stimulation of the ear"</li> <li>▪ In Item 10 added "type" to read "botulinum toxin type A injections"</li> <li>▪ Removed "electrical stimulation"</li> </ul>
	Rational section updated
	References updated

**REFERENCES**

1. Pichora-Fuller MK, Santaguida P, Hammill A, et al. Evaluation and Treatment of Tinnitus: Comparative Effectiveness. Comparative Effectiveness Review No. 122. (Prepared by the McMaster University Evidence-based Practice Center under Contract No. 290-2007-10060-I) AHRQ Publication No. 13-EHC110-EF. Rockville, MD: Agency for Healthcare Research and Quality; August 2013. [www.effectivehealthcare.ahrq.gov/reports/final.cfm](http://www.effectivehealthcare.ahrq.gov/reports/final.cfm). Accessed March, 2015.

2. Cima RF, Maes IH, Joore MA, et al. Specialised treatment based on cognitive behaviour therapy versus usual care for tinnitus: a randomised controlled trial. *Lancet*. May 26 2012;379(9830):1951-1959. PMID 22633033
3. Martinez Devesa P, Waddell A, Perera R, et al. Cognitive behavioural therapy for tinnitus. *Cochrane Database Syst Rev*. 2007(1):CD005233. PMID 17253549
4. Martinez-Devesa P, Perera R, Theodoulou M, et al. Cognitive behavioural therapy for tinnitus. *Cochrane Database Syst Rev*. 2010(9):CD005233. PMID 20824844
5. Grewal R, Spielmann PM, Jones SE, et al. Clinical efficacy of tinnitus retraining therapy and cognitive behavioural therapy in the treatment of subjective tinnitus: a systematic review. *J Laryngol Otol*. Dec 2014;128(12):1028-1033. PMID 25417546
6. Zenner HP, Vonthein R, Zenner B, et al. Standardized tinnitus-specific individual cognitive-behavioral therapy: a controlled outcome study with 286 tinnitus patients. *Hear Res*. Apr 2013;298:117-125. PMID 23287811
7. Westin VZ, Schulin M, Hesser H, et al. Acceptance and commitment therapy versus tinnitus retraining therapy in the treatment of tinnitus: a randomised controlled trial. *Behav Res Ther*. Nov 2011;49(11):737-747. PMID 21864830
8. Kaldo V, Cars S, Rahnert M, et al. Use of a self-help book with weekly therapist contact to reduce tinnitus distress: a randomized controlled trial. *J Psychosom Res*. Aug 2007;63(2):195-202. PMID 17662757
9. Kaldo V, Levin S, Widarsson J, et al. Internet versus group cognitive-behavioral treatment of distress associated with tinnitus: a randomized controlled trial. *Behav Ther*. Dec 2008;39(4):348-359. PMID 19027431
10. Hesser H, Gustafsson T, Lunden C, et al. A randomized controlled trial of Internet-delivered cognitive behavior therapy and acceptance and commitment therapy in the treatment of tinnitus. *J Consult Clin Psychol*. Aug 2012;80(4):649-661. PMID 22250855
11. Jasper K, Weise C, Conrad I, et al. Internet-based guided self-help versus group cognitive behavioral therapy for chronic tinnitus: a randomized controlled trial. *Psychother Psychosom*. 2014;83(4):234-246. PMID 24970708
12. Hobson J, Chisholm E, El Refaie A. Sound therapy (masking) in the management of tinnitus in adults. *Cochrane Database Syst Rev*. 2010(12):CD006371. PMID 21154366
13. Hobson J, Chisholm E, El Refaie A. Sound therapy (masking) in the management of tinnitus in adults. *Cochrane Database Syst Rev*. 2012;11:CD006371. PMID 23152235
14. Jalilvand H, Pourbakht A, Haghani H. Hearing aid or tinnitus masker: which one is the best treatment for blast-induced tinnitus? The results of a long-term study on 974 patients. *Audiol Neurootol*. 2015;20(3):195-201. PMID 25924663
15. Hoare DJ, Kowalkowski VL, Kang S, et al. Systematic review and meta-analyses of randomized controlled trials examining tinnitus management. *Laryngoscope*. Jul 2011;121(7):1555-1564. PMID 21671234
16. Bauer CA, Brozoski TJ. Effect of tinnitus retraining therapy on the loudness and annoyance of tinnitus: a controlled trial. *Ear Hear*. Mar-Apr 2011;32(2):145-155. PMID 20890204
17. Henry JA, Schechter MA, Zaugg TL, et al. Clinical trial to compare tinnitus masking and tinnitus retraining therapy. *Acta Otolaryngol Suppl*. Dec 2006(556):64-69. PMID 17114146
18. Phillips JS, McFerran D. Tinnitus Retraining Therapy (TRT) for tinnitus. *Cochrane Database Syst Rev*. 2010;3:CD007330. PMID 20238353
19. Davis PB, Wilde RA, Steed LG, et al. Treatment of tinnitus with a customized acoustic neural stimulus: a controlled clinical study. *Ear Nose Throat J*. Jun 2008;87(6):330-339. PMID 18561116

20. Hanley PJ, Davis PB, Paki B, et al. Treatment of tinnitus with a customized, dynamic acoustic neural stimulus: clinical outcomes in general private practice. *Ann Otol Rhinol Laryngol*. Nov 2008;117(11):791-799. PMID 19102123
21. Herraiz C, Diges I, Cobo P, et al. Auditory discrimination training for tinnitus treatment: the effect of different paradigms. *Eur Arch Otorhinolaryngol*. Jul 2010;267(7):1067-1074. PMID 20044759
22. Okamoto H, Stracke H, Stoll W, et al. Listening to tailor-made notched music reduces tinnitus loudness and tinnitus-related auditory cortex activity. *Proc Natl Acad Sci U S A*. Jan 19 2010;107(3):1207-1210. PMID 20080545
23. Argstatter H, Grapp M, Hutter E, et al. The effectiveness of neuro-music therapy according to the Heidelberg model compared to a single session of educational counseling as treatment for tinnitus: a controlled trial. *J Psychosom Res*. Mar 2015;78(3):285-292. PMID 25224125
24. Soleimani R, Jalali MM, Hasandokht T. Therapeutic impact of repetitive transcranial magnetic stimulation (rTMS) on tinnitus: a systematic review and meta-analysis. *Eur Arch Otorhinolaryngol*. May 13 2015. PMID 25968009
25. Langguth B, Landgrebe M, Frank E, et al. Efficacy of different protocols of transcranial magnetic stimulation for the treatment of tinnitus: Pooled analysis of two randomized controlled studies. *World J Biol Psychiatry*. May 2014;15(4):276-285. PMID 22909265
26. Folmer RL, Theodoroff SM, Casiana L, et al. Repetitive Transcranial Magnetic Stimulation Treatment for Chronic Tinnitus: A Randomized Clinical Trial. *JAMA Otolaryngol Head Neck Surg*. Aug 2015;141(8):716-722. PMID 26181507
27. Song JJ, Vanneste S, Van de Heyning P, et al. Transcranial direct current stimulation in tinnitus patients: a systemic review and meta-analysis. *ScientificWorldJournal*. 2012;2012:427941. PMID 23133339
28. Pal N, Maire R, Stephan MA, et al. Transcranial Direct Current Stimulation for the Treatment of Chronic Tinnitus: A Randomized Controlled Study. *Brain Stimul*. Nov-Dec 2015;8(6):1101-1107. PMID 26198363
29. Dobie RA, Hoberg KE, Rees TS. Electrical tinnitus suppression: a double-blind crossover study. *Otolaryngol Head Neck Surg*. Oct 1986;95(3 Pt 1):319-323. PMID 3108780
30. Thedinger BS, Karlsen E, Schack SH. Treatment of tinnitus with electrical stimulation: an evaluation of the Audimax Theraband. *Laryngoscope*. Jan 1987;97(1):33-37. PMID 3491942
31. Mielczarek M, Olszewski J. Direct current stimulation of the ear in tinnitus treatment: a double-blind placebo-controlled study. *Eur Arch Otorhinolaryngol*. Jun 2014;271(6):1815-1822. PMID 24337877
32. Nakashima T, Ueda H, Misawa H, et al. Transmeatal low-power laser irradiation for tinnitus. *Otol Neurotol*. May 2002;23(3):296-300. PMID 11981384
33. Teggi R, Bellini C, Piccioni LO, et al. Transmeatal low-level laser therapy for chronic tinnitus with cochlear dysfunction. *Audiol Neurootol*. 2009;14(2):115-120. PMID 18843180
34. Ngao CF, Tan TS, Narayanan P, et al. The effectiveness of transmeatal low-power laser stimulation in treating tinnitus. *Eur Arch Otorhinolaryngol*. May 2014;271(5):975-980. PMID 23605244
35. Dehkordi MA, Einolghozati S, Ghasemi SM, et al. Effect of low-level laser therapy in the treatment of cochlear tinnitus: a double-blind, placebo-controlled study. *Ear Nose Throat J*. Jan 2015;94(1):32-36. PMID 25606834
36. Ghossaini SN, Spitzer JB, Mackins CC, et al. High-frequency pulsed electromagnetic energy in tinnitus treatment. *Laryngoscope*. Mar 2004;114(3):495-500. PMID 15091224

37. Stidham KR, Solomon PH, Roberson JB. Evaluation of botulinum toxin A in treatment of tinnitus. *Otolaryngol Head Neck Surg.* Jun 2005;132(6):883-889. PMID 15944559
38. Tunkel DE, Bauer CA, Sun GH, et al. Clinical practice guideline: tinnitus *Otolaryngol Head Neck Surg.* 2014 Oct;151(2 Suppl):S1-S40.  
[http://oto.sagepub.com/cgi/collection/clinical\\_practice\\_guidelines\\_consensus\\_statements\\_practice\\_parameters\\_continuous\\_quality\\_improvement](http://oto.sagepub.com/cgi/collection/clinical_practice_guidelines_consensus_statements_practice_parameters_continuous_quality_improvement). Accessed March 17, 2016.