Treatment of Tinnitus

Description

A variety of non-pharmacologic treatments are being evaluated to improve the subjective symptoms of tinnitus. These approaches include use of tinnitus maskers, electrical stimulation, transmeatal laser irradiation, electromagnetic energy, tinnitus-retraining therapy, tinnitus coping therapy, transcranial magnetic stimulation, transcutaneous electrical stimulation, sound therapy, 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 as a malfunction in the processing of auditory signals. A hearing impairment, often noise-induced or related to aging, is commonly associated with tinnitus. Clinically, tinnitus is subdivided into subjective and objective; 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 idiopathic, subjective, and frequently self-limited. In a small subset of patients with subjective tinnitus, its 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 (TRT), also referred to as tinnitus habituation therapy, is based on the theories of a researcher named Jastreboff. Jastreboff proposes that tinnitus itself is related to the normal background electrical activity in auditory nerve cells, but the key factor in some patient’s unpleasant response to the noise is due to a spreading of the signal and an abnormal conditioned reflex in the extra-auditory limbic and autonomic nervous systems. The goal of tinnitus-retraining therapy is to habituate (retrain) the subcortical and cortical response to the auditory neural activity. In contrast to tinnitus masking, the auditory stimulus is not intended to drown out or mask the tinnitus but is set at a level such that the tinnitus can still be detected. This strategy is thought to enhance extinction of the 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.

Transcutaneous electrical stimulation to the external ear has also been investigated and is based on the observation that the 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 has been cleared for marketing as a tinnitus masker through the U.S. Food and Drug Administration’s (FDA) 510(k) process and 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.”

Related Policies

2.01.50 Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders
2.01.56 Low Level Laser Therapy
5.75.01 Botox
7.01.83 Auditory Brainstem Implant

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Treatment of tinnitus with tinnitus coping therapy, tinnitus maskers, tinnitus retraining therapy, customized sound therapy, transcranial magnetic stimulation, transcranial direct current stimulation, electrical transcutaneous electrical stimulation of the ear, transmeatal laser irradiation, electromagnetic energy, and botulinum toxin type A injections is considered not medically necessary.
Note: This policy does not address surgical (eg, cochlear or brainstem implants) or pharmacologic treatment of tinnitus (eg, use of amitriptyline or other tricyclic antidepressants).

### Rationale

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 (AHRQ) published a comparative effectiveness review on the evaluation and treatment of tinnitus. (1) 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, wait 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. Evidence was insufficient for other psychological and behavioral interventions such as tinnitus retraining therapy and relaxation.

### Tinnitus 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. (2) Out of 741 untreated patients who were screened, 247 were assigned to usual care (e.g., 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 cognitive and behavioral therapy (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, the specialized care resulted in a modest improvement in health-related quality of life (effect size of 0.24), decrease in tinnitus severity (effect size of 0.43) and decrease in tinnitus impairment (effect size of 0.45). Since the specialized care protocol was an intensive, multidisciplinary intervention, it is uncertain which components of the intervention 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 randomized trials in which 285 patients with tinnitus received cognitive behavioral therapy (CBT) or a control condition (another treatment or waiting list). (3)
Analysis found no significant effect in the subjective loudness of tinnitus or in the associated depression. However, there was an improvement in the quality of life (global tinnitus severity), suggesting that cognitive behavioral therapy (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. (4) As was previously found, there was no significant difference in subjective tinnitus loudness between cognitive behavioral therapy and either no treatment or another intervention but an improvement in quality of life. The updated analysis found evidence that depression scores improved when comparing cognitive behavioral therapy to no treatment, but there was no evidence of benefit in depression scores when compared to other treatments (yoga, education, and minimal contact-education). No additional RCTs were identified in a 2014 systematic review of the literature. (5)

In 2013, Zenner et al reported a multicenter pragmatic trial of a standardized individual tinnitus-specific CBT program versus a wait-list control in 286 patients between 14 and 78 years of age. (6) 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 of 3.4 (95% confidence interval 2.6 to 4.5) in intent-to-treat analysis. Improvement in the tinnitus change score with a score of 2 or better was reported in 85% of CBT-treated patients compared to 22% of controls. Another primary outcome, the multivariate rank of the Tinnitus Handicap Inventory (THI) improved significantly in the treatment group but not in the control group. These scales appear to have been developed and tested for validity in a prior study by the authors of this report. Interpretation of this study 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 normal hearing patients. (7) 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 Tinnitus Handicap Inventory (THI) was the primary outcome measure, 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, the THI improved from 45.27 to 28.19 at 18 months. 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. Improvement on the THI was found for 54.5% in the ACT group and 20% in the tinnitus retraining group (p<0.04).

Self-help and Internet-based Coping Therapies
A 2007 study by Kaldo et al., found that a cognitive behavioral therapy (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
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 randomized study 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 studies were followed by a 2012 randomized controlled trial 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). 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-min 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 waitlist 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. 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. (14)

**Tinnitus Retraining Therapy**

A 2011 systematic review identified 3 RCTs using tinnitus retraining therapy. (15) 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. (7) 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). (16) 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. (17) 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. (5,18)

Customized Sound Therapy

Four randomized or pseudo-randomized controlled trials have been identified on 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. (19) 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. (20) 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 and colleagues randomized 45 patients scoring mild or moderate on the Tinnitus Handicap Inventory (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). (21) 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 patients (91%) completed training and follow-up questionnaires. Four percent of patients in the waiting-list control group reported their tinnitus to be better, compared to 42% of patients reporting improvement following auditory discrimination training. The self-reported improvement in tinnitus tended to be higher in the NONSAME group (54%) in comparison with the SAME group (26%), although subjective improvement was variable, and the difference was not statistically different. The subjective improvement in VAS tinnitus intensity was modest and similar in the two 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 frequency (2.11).

Notched Music

In another publication from 2010, Okamoto 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. (22) 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 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.

**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-min 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 Tinnitus Questionnaire (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 to 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. (24) 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). (25) 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.26 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. (27) Six studies (3 sham-controlled RCTs, 3 uncontrolled, open-label studies) were included in the review. Stimulation areas included the left temporal area and bifrontal tDCS. Overall, there was a 39.5% response rate (criteria for responder was not defined), with a mean reduction of tinnitus intensity of 13.5%. Effects were similar for stimulation over the left temporal area compared to bifrontal tDCS. 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. (28) 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 electrical stimulation were reported in the 1980s with negative results. Dobie and colleagues reported on a randomized, double-blind crossover trial in which 40 patients received an active or disconnected placebo device. (29) Reduction in severity of tinnitus was reported in 2 of 20 patients with the active device and 4 of 20 patients with the placebo device. Fifteen of the 20 patients reported no effect with either device. Thedinger and colleagues reported on a single-blind crossover trial of 30 patients who received active or placebo stimulation over 2 weeks. Only 2 of the 30 subjects obtained a true-positive result. (30) 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.31 Directly after treatment, tinnitus improved in 37.8% of the active treatment group versus 30.8% of the control group ($X^2$ 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, (32) in a 2009 placebo-controlled, double-blind RCT with 60 patients, (33) a 2014
placebo-controlled, double-blind RCT with 48 patients, (34) and a 2015 placebo-controlled, double-blind RCT with 66 patients. (35)

**Electromagnetic Energy**

Ghossaini and colleagues reported on a randomized, double-blind placebo-controlled study of 37 patients who received either placebo treatment or electromagnetic energy treatment with a Diapulse device for 30 minutes, 3 times a week for 1 month. (36) The authors found no significant changes in either group in pretreatment and post-treatment audiometric thresholds, Tinnitus Handicap Inventory scores or tinnitus rating scores, and concluded pulsed electromagnetic energy (at 27.12 MHz at 600 pulses/second) offered no benefit in the treatment of tinnitus.

**Botulinum Toxin A**

Stidham and colleagues explored the use of botulinum toxin A injections for tinnitus treatment under the theory that blocking the autonomic pathways could reduce the perception of tinnitus. (37) In their study, 30 patients were randomized in a double-blind study 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 (23%) of 26 patients had reduced tinnitus after the botulinum toxin 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 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 policy are listed in Table 1.

### Table 1. Summary of Key Trials

<table>
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<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>Study Protocol for a CBT-based Internet Intervention for Adults With Tinnitus in the United Kingdom: A Randomised Controlled Trial</td>
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<td>Internet-based Versus Face-to-face Clinical Care for Tinnitus: A Multi-study Randomised Control Trial</td>
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<td>Tinnitus Retraining Therapy Trial</td>
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<td>NCT02408575</td>
<td>Hearing Aids With “Notched Amplification” for the Treatment of Chronic Tinnitus - A Controlled Randomized Pilot Study on Safety, Tolerability and Clinical Performance</td>
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NCT: national clinical trial.

### Supplemental Information

#### 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: (38)

- 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 (≥ 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.

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.

Medicare National Coverage

The Centers for Medicare and Medicaid (CMS) has a longstanding national coverage determination for tinnitus masking. This is 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. Therefore, it is not covered.

References


# Treatment of Tinnitus

**Effective Date:** July 15, 2015  
**Original Policy Date:** December 7, 2011  
**Subject:** Treatment of Tinnitus  
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## Policy History

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<td>June 2012</td>
<td>Update Policy</td>
<td>Policy updated with literature search; references added and reordered; policy statement unchanged.</td>
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<tr>
<td>September 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature search. References 1, 5, 11, 22, 27, 38, 42-43, and 46 added; Policy statement unchanged.</td>
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<tr>
<td>June 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature search; references 14, 24-26, and 28 added; some references removed. Policy statement reordered and &quot;surgical&quot; added to the note on topics that the policy does not address.</td>
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## Keywords

- Masking Device, Tinnitus
- Sound Therapy
- Tinnitus, Treatment of

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 16, 2016 and is effective October 15, 2016.

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**Signature on File**

Deborah M. Smith, MD, MPH