Medical Policy

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Title: Treatment of Tinnitus

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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, cognitive and behavioral therapies, 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 a malfunction in the processing of auditory signals. A hearing impairment, often noise-induced or related to aging, is commonly associated with

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tinnitus. Clinically, tinnitus is subdivided into subjective and objective; the latter describes the minority of cases in which an external stimulus is potentially heard by an observer, for example by placing a stethoscope over the patient's external ear. Common causes of objective tinnitus include middle ear and skull-based tumors, vascular abnormalities, and metabolic derangements. In the majority of cases, tinnitus is subjective and frequently self-limited. In a small subset of patients with subjective tinnitus, its 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 a researcher named Jastreboff. Jastreboff proposed that tinnitus itself is related to the normal background electrical activity in auditory nerve cells, but the key factor is the subject's unpleasant perception of the noise, which is governed by an abnormal conditioned response in the extra-auditory limbic system. The goal of tinnitus-retraining therapy is to retrain the subcortical and cortical centers involved in processing the tinnitus signals and habituate 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 habituation to the tinnitus by increasing the 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.

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.

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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."

POLICY

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

1. tinnitus maskers
2. electrical stimulation
3. transmeatal laser irradiation
4. electromagnetic energy
5. tinnitus-retraining therapy
6. tinnitus coping therapy
7. transcranial magnetic stimulation
8. transcutaneous electrical stimulation
9. sound therapy, or
10. botulinum toxin A injections

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. This literature review was updated through April 18, 2013.

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. (1) 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, multi-disciplinary 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.

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Cognitive Behavioral Therapy: A 2007 Cochrane review identified 6 randomized trials in which 285 patients with tinnitus received cognitive behavioral therapy or a control condition (another treatment or waiting list). (2) 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 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. (3) 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).

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. (4) 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 self-help book for tinnitus combined with 7 weekly phone calls from a therapist reduced distress (greater than 50% on the tinnitus reaction questionnaire) in 32% of subjects compared with 5% of the waiting-list control group. (5) 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. (6)

These studies were followed by a 2012 randomized controlled trial of internet-delivered CBT or ACT. (7) 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.

Tinnitus Masking

A 2010 Cochrane review, with an update in 2012, evaluated evidence for masking in the management of tinnitus in adults. (8, 9) Included in the review were 6 randomized controlled trials ([RCTs] 553 participants) that used noise-generating devices or hearing aids as the sole

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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.

For example, Stephens and Corcoran reported on a controlled study that assigned non-hearing-impaired subjects to either a control group (n=24) with limited counseling or a treatment group consisting of counseling in addition to the use of 1 of 2 different tinnitus maskers (n=51). (10) Outcomes were assessed with a questionnaire. There were no significant differences among the control and treatment groups, leading the authors to conclude that treatment with maskers has not been found to show a significant advantage compared to counseling alone. No studies were identified that compared tinnitus masking using specialized ear-worn devices with other more widely available auditory stimuli (e.g., radios or music players). Erlandsson et al. performed a clinical trial in which patients were randomized to receive either a masker or sham device; those receiving the sham device were falsely told that it delivered a beneficial electrical current. (11) Treatment response was based on responses to a questionnaire focusing on both changes in tinnitus level and nonspecific effects on mood, stress, and symptoms other than tinnitus. Neither the treatment nor the placebo group reported a significant change in tinnitus intensity.

Tinnitus Retraining Therapy

While Jastreboff and Hazell had published the theoretical rationale behind tinnitus retraining therapy, no controlled trials were identified at the time this policy was created. Other articles were identified, (12-14) but these studies were either focused on tools to evaluate the results of tinnitus retraining or consisted of uncontrolled trials. A 2011 systematic review identified 3 randomized controlled trials (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 multi-component intervention that included tinnitus retraining. Additional controlled studies are described below.

The RCT by Westin et al. (described above) reported results of tinnitus retraining compared to acceptance and commitment therapy (ACT) or waiting-list control in 64 normal hearing patients. (4) 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. The THI improved from 45.27 to 28.19 at 18 months in the ACT group. 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. These findings are limited by the lack of a placebo-control group

In 2011, Bauer and Bozoski reported a quasi-randomized 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 gender. Participants were assigned to 8 hours daily tinnitus retraining with 3 one-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

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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. The THI improved over the 18 months of the study to a similar extent for both the active and sham tinnitus retraining therapy. Subjective loudness was reduced in the tinnitus retraining group compared to controls at 12 to 18 months, but there was no between-group difference in the rating of annoyance and distress.

Another quasi-randomized trial from a Veterans Administration (VA) 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 to 5 hours total). At each visit, the subjects completed the THI, Tinnitus Handicap Questionnaire, 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 to 0.66) were reached for the tinnitus-retraining therapy and, after 18 months of treatment, major effect sizes (0.77 to 1.26) were obtained. Post hoc analysis suggested that improvements were greatest in subjects who initially rated tinnitus as a “very big problem” with effect sizes of 2.01 for tinnitus severity and 2.05 for tinnitus handicap index. In comparison, tinnitus-masking therapy resulted in medium effect sizes (0.5 and 0.62) in this subgroup analysis. The authors noted that several confounding variables were present in this study, including differences in counseling between the two groups, and that a multicenter continuation study in the VA setting is being conducted. This is the only trial that met selection criteria for a 2010 Cochrane review; the summary stated that this single, low-quality trial suggests that tinnitus-retraining therapy is more effective than tinnitus masking, but since only a single trial was identified, and that trial had methodologic flaws particularly with respect to allocation bias, it is not possible to reach a firm conclusion regarding this treatment. (18)

In summary, the literature 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 to active or sham controls.

Customized Sound Therapy

Three randomized or pseudo-randomized controlled trials have been identified on customized sound therapy.

An 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 to 23). Patients were allocated into 1 of 4 groups, 1) customized acoustic stimulus at high intensity for 2 hours per day, 2) customized acoustic stimulus at a lower intensity, 3) tinnitus-retraining therapy with a broadband stimulator and counseling, or 4) counseling alone. Subjects were instructed to listen to the devices for 2 hours per day at the time of day when symptoms were most severe and at a level that completely

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(Group 1) or partially (Group 2) masked the tinnitus; use of the devices averaged 1.8 hours per day (range 0.4 to 6.8). The 2 customized acoustic stimuli groups were combined in the analysis due to overlap in the self-administered stimulus intensity (absence of statistical difference between the groups). All patients lost to follow-up were included in the dataset for analysis with a "last value carried forward." Mean scores on the Tinnitus Reaction Questionnaire (TRQ) improved over the 12 months of the study for the customized acoustic stimuli. TRQ scores were not significantly improved in the control groups. At the 6-month follow-up, 86% of patients in the customized acoustic stimuli groups had met the definition of success based on 40% improvement in TRQ scores. Normalized visual analogue scores (VAS) for tinnitus severity, general relaxation, and loudness tolerance were improved relative to both baseline and the control group's scores at 12 months. Perceived benefits were also greater with the customized acoustic stimulus.

Another publication from the developers of the device described results for the first 552 patients who had 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 one or more of the following: psychological disturbance, a low level of tinnitus-related disturbance (TRQ score less than 17) and/or moderately severe or severe hearing loss in one ear (greater than 50 dB). Tier 3 (92 patients) exhibited one or more of the following: "reactive" tinnitus, continued exposure to high levels of noise during treatment, active pursuit of compensation, multi-tone tinnitus, pulsatile tinnitus, Meniere's disease, and/or hearing loss of greater than 50 decibels (dBs) in both ears. Of the 552 patients who began therapy, 62 (11%) chose to discontinue treatment for refund and 20 (4%) were lost to follow-up. After an average treatment duration of 37 weeks, the TRQ was reported to be improved (by greater than 40%) in 92% of tier 1 patients, 60% of tier 2 patients, and 39% of tier 3 patients. It was not reported if the reduction in symptoms persisted when treatment stopped. Controlled studies with long-term follow-up are needed to evaluate the durability of treatment and the relative contribution of generalized masking versus desensitization to these results.

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).

In another publication from 2010, Okamato et al. reported a small (n=24) double-blinded pseudo-randomized trial that compared 12 months of listening to notched music (the tinnitus frequency was removed) or placebo music. (22) An additional group of patients who were not

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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.

In summary, 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 above utilize 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. In addition, patients in these studies were highly selected to maximize treatment effects. No studies from the U.S. were identified.

Transcranial Magnetic Stimulation

A 2011 Cochrane review included 5 sham-controlled trials (233 patients) with parallel groups that examined repetitive transcranial magnetic stimulation (rTMS) for the treatment of tinnitus. (23) Each study described the use of a different rTMS device that delivered different frequencies ranging from 1 Hz to 25 Hz. All of the studies were relatively small but were considered to have a low risk of bias. Four trials reported tinnitus severity and disability using the THI; only one study demonstrated a statistically significant improvement in THI scores. Pooled results of 2 studies that used a self-rating scale showed a statistically significant reduction in tinnitus loudness (risk ratio: 4.17, 95% confidence interval: 1.30 to 13.40). However, the validity of these pooled results were limited since one trial had a risk of selection bias and the confidence interval of these 2 small trials (n=37 and 54) was wide. This analysis indicates that there is very limited support for the use of low-frequency rTMS for tinnitus and that larger placebo-controlled double-blind studies are needed to confirm the effectiveness of rTMS for tinnitus. Further study is also needed regarding the durability of the effect. (24)

One of the studies included in the systematic reviews was by Anders et al., who published results of a double-blinded randomized sham-controlled trial with 42 patients who had chronic, treatment-resistant tinnitus and completed 2 weeks of rTMS treatment over the left primary auditory cortex in 2010. (25) An additional 10 patients withdrew from the study before the end of treatment due to adverse effects such as headache, worsening of tinnitus, or perceived lack of efficacy. Tinnitus severity was measured at baseline, the end of treatment (week 2), and during follow-up at 6, 14, and 26 weeks. The baseline THI was 37.1 for the active treatment and 26.5 for the sham treatment. At the end of the stimulation phase, both active and sham groups showed a significant reduction in the symptoms of tinnitus, as measured by the THI and Tinnitus Questionnaire. In the active rTMS group, tinnitus severity with the THI was rated as 31.8 at 2 weeks, increasing to around 33 through the 26 weeks of follow-up. In the sham group, the THI was 23.1 at week 2, rising to 27.7 by 26 weeks. A similar pattern was observed with the Tinnitus Questionnaire. Interpretation of this study is limited due to the differences in baseline scores and

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improvement in the sham group immediately following treatment. In addition, the clinical significance of a 4-point change in the THI and 3-point change in the Tinnitus Questionnaire is unclear.

Another small (n=19) randomized double-blinded sham-controlled parallel trial by Marcondes et al. evaluated 6-month follow-up after rTMS. (26) As earlier studies showed improved outcomes in the absence of hearing impairment, only subjects with normal pure tone audiometry were included in this trial. Five sessions of rTMS (17 minutes per session) were performed on 5 consecutive business days. Placebo stimulation was performed with a sham coil system, which mimics the sound of active stimulation, without producing a magnetic field. Tinnitus severity on the THI showed a decrease from baseline (29.8) to 1-month (19.4) and 6-month (22.8) follow-up. There was no change in the THI following sham stimulation (28.9 at baseline, 28.9 at 1 month, and 29.6 at 6 months). At 6-month follow-up, 40% of patients receiving rTMS had a reduction greater than 10 points in the THI, compared to 22% after sham rTMS. There was a modest decrease in the mean VAS for tinnitus loudness for active rTMS, and some differences between groups in objectively measured changes in blood flow in the temporal and limbic lobes with single-photon emission computed tomography (SPECT) imaging. Although these longer-term results are intriguing, additional studies with a larger number of subjects are needed to adequately evaluate the efficacy of this treatment.

Several sham-controlled crossover trials have also been reported (not included in the Cochrane review). One randomized, double-blind, sham-controlled crossover trial (16 patients) used low-frequency (1Hz) rTMS over the auditory association cortex (left temporoparietal region) for 5 days, with 2 weeks follow-up after (and between) each condition. (27) Two patients dropped out due to worsening of tinnitus (one from each condition); sham treatment resulted in a less than 10% improvement in VAS over the 3-week assessment. The average improvement in VAS for active rTMS (about 35%) was maintained for 1 week following treatment. Of the 14 patients who completed the study, 8 (57%) were classified as responders (25% or greater improvement in VAS); no baseline factors were found to be associated with a positive response. Kleinjung et al. reported on a placebo-controlled crossover study of low-frequency rTMS in 14 patients with chronic tinnitus. (28) Using a Magstim system, the authors applied rTMS to the area of increased metabolic activity in the auditory cortex, as identified by fused positron emission tomography (PET) and magnetic resonance imaging (MRI) data. After 1 week of rTMS, 11 of 14 patients experienced a significant reduction in tinnitus ($p<0.005$), whereas the sham treatment did not result in a significant change. Eight patients also reported reduced tinnitus 6 months after treatment.

In summary, the literature on rTMS for tinnitus consists of a number of small randomized sham-controlled trials with either parallel or crossover designs. Results from these trials are mixed, with some trials not finding a statistically significant effect of rTMS on tinnitus severity. Overall, the literature provides limited support for the use of rTMS. Larger controlled trials are needed to permit conclusions regarding the effect of this technology on health outcomes.

Transcranial Direct Current Stimulation

In 2012, Song et al. published a systematic review of transcranial direct current stimulation (tDCS) for the treatment of tinnitus. (29) Six studies (3 open-label and 3 RCTs) 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

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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.

Transcutaneous 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. 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. (30) 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. (31) Steenerson and Cronin reported on a large case series of 500 patients with tinnitus who were treated with electrical stimulation twice weekly for a total of 6 to 10 visits. (32) Fifty-three percent of patients reported a significant benefit, defined as an improvement of at least 2 points on a 10-point scale of tinnitus intensity. Despite the favorable results, case series cannot be used as evidence of treatment efficacy, particularly when a placebo effect is anticipated. Literature review updates failed to identify any additional randomized studies that would alter the conclusions reached here. Thus, the policy statement regarding transcutaneous electrical stimulation of the ear is unchanged.

Transmeatal Laser Irradiation

A randomized study from 2002 reported that there was no significant difference in tinnitus between the active or placebo group. (33) In a 2005 update, Tauber and colleagues reported on the use of transmeatal low-level laser therapy for the treatment of chronic tinnitus in 35 patients randomized to receive 5 single-diode laser treatments at either 635 or 830 nm. (34) The authors reported 13 of 35 patients had reduced tinnitus loudness, while 2 patients reported absence of tinnitus. However, this was not a placebo-controlled trial, and the authors noted that further study was needed. A 2008 publication of a randomized placebo-controlled double-blind study with 60 patients reported no efficacy of laser therapy for tinnitus. (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. The authors reported 7 patients had reduced tinnitus after the botulinum toxin A injections, which was statistically significant when compared to the placebo groups in which only 2 patients reported reduced

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tinnitus (p<0.005). The tinnitus handicap inventory scores were also significantly decreased between pretreatment and 4 months post-botulinum toxin A injections. However, no other significant differences were noted when comparing the treatments at 1 and 4 months after injections. The authors noted that larger studies are needed. Also, study limitations including size and lack of intent-to-treat analysis limited interpretation of the results.

Summary

A variety of treatments have been evaluated for the treatment of tinnitus. Cognitive and behavioral coping therapies have been reported 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 it is uncertain if the intensive treatment approach used could be replicated outside of the investigational setting. Other RCT results suggest that a self-help/internet-based approach to cognitive and behavioral therapy (CBT) or acceptance and commitment therapy (ACT) may also improve coping skills. Additional studies are needed to determine the most effective method of delivering psychological coping therapy outside of the investigational setting. As a result, tinnitus coping therapy, such as cognitive behavioral interventions and ACT, are considered investigational.

Current evidence is insufficient to show improved health outcomes in patients treated with tinnitus maskers, electrical stimulation, transmeatal laser irradiation, electromagnetic energy, tinnitus-retraining therapy, sound therapy, transcranial magnetic stimulation, transcutaneous electrical stimulation, or botulinum toxin A injections. Therefore, these treatments are considered investigational.

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.

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- There is no specific CPT code for low-level laser therapy. However, providers may elect to use CPT code 97026 since 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: ▪ Added the following experimental / investigational treatments to the policy: tinnitus coping therapy, transcutaneous electrical stimulation, sound therapy
	Rationale section updated
	In Coding section: ▪ Added the following CPT / HCPCS codes: 92507, 92625, 97014, E0720, S8948
	References updated
01-15-2013	In the Coding section: ▪ In bullet #1, removed "90804-90809" and inserted "90832-90838" (Effective 12-31-2012)
11-12-2013	Description section updated
	Rationale section updated
	In Coding section ▪ 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.
	References updated

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