Treatment of Tinnitus

Policy Number: 8.01.39  Last Review: 9/2018

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Treatment of Tinnitus when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Psychological coping therapy including cognitive behavioral therapy, self-help cognitive behavioral therapy, tinnitus coping therapy, acceptance and commitment therapy and psychophysiological treatment may be considered medically necessary for persistent and bothersome tinnitus.

When Policy Topic is not covered
Treatment of tinnitus with any of the following therapies is considered investigational:
- biofeedback
- tinnitus maskers, customized sound therapy
- combined psychological and sound therapy (e.g., tinnitus retraining therapy)
- transcranial magnetic stimulation,
- transcranial direct current stimulation
- electrical transcutaneous electrical stimulation of the ear, electromagnetic energy,
- transmeatal laser irradiation

NOTE: This policy does not address surgical (e.g., cochlear or brainstem implants) or pharmacologic treatment of tinnitus, e.g., the use of amitriptyline or other tricyclic antidepressants or injection of botulinum toxin.

Description of Procedure or Service

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<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
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<td>With persistent, bothersome tinnitus</td>
<td>Psychological coping therapy</td>
<td>Standard therapy</td>
<td>Symptoms</td>
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<td>Functional outcomes</td>
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<td>Quality of life</td>
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<td>Treatment-related morbidity</td>
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Various nonpharmacologic treatments are being evaluated to improve the subjective symptoms of tinnitus. These approaches include cognitive and behavioral coping therapies, sound therapies, combined psychological and sound therapies, repetitive transcranial magnetic stimulation, electrical and electromagnetic stimulation, and transmeatal laser irradiation.

For individuals who have persistent, bothersome tinnitus who receive psychological coping therapy, the evidence includes a number of randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. These therapies are intended to reduce tinnitus impairment and improve health-related quality of life. Meta-analyses of a variety of different cognitive and behavioral therapies find an improvement in global tinnitus severity and quality of life, even when tinnitus loudness is not affected. Other RCTs report that a self-help/Internet-based approach to cognitive and behavioral therapy or acceptance and commitment therapy may also improve coping skills. The evidence is sufficient to determine that the technology results in a meaningful improvement in health outcomes.

For individuals who have tinnitus who receive sound therapy the evidence includes RCTs and a systematic review of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence
on tinnitus masking includes 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. 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. A 2016 study that was double-blinded and adequately powered found no benefit of notched music on the primary outcome measures of tinnitus perception and tinnitus distress, although the subcomponent score of tinnitus loudness was reported to be reduced. A benefit on tinnitus loudness but not tinnitus perception or tinnitus distress is of uncertain significance and may be spurious, and would need to be corroborated in additional studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have tinnitus who receive combined psychological and sound therapy, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on tinnitus retraining therapy consists of a number of small randomized or quasi-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. For Heidelberg neuromusic therapy there is 1 trial that used an investigator-blinded RCT design and showed positive short-term results following treatment. However, the durability of treatment is also unknown. A large, multicenter RCT trial using an intensive, multidisciplinary intervention showed improvement in outcomes. It is uncertain whether the multiple intensive interventions utilized in this trial could be replicated outside of the investigational setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have tinnitus who receive transcranial magnetic stimulation, the evidence includes a number of small- to moderate-sized RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Results from these studies are mixed, with some trials reporting a statistically significant effect of repetitive transcranial magnetic stimulation on tinnitus severity and others reporting no significant difference. Larger controlled trials with longer follow-up are needed for this common condition. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have tinnitus who receive electrical or electromagnetic stimulation, the evidence includes a number of sham-controlled RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The available evidence does not currently support use of these treatments. A 2015 sham-controlled study that was adequately powered found no benefit of transcranial direct current stimulation (tDCS). Moreover, a 2017 meta-analysis found some benefit for tDCS, however, it was noted that further study was needed to evaluate tDCS as a treatment option. Studies have not shown a benefit for direct current electrical stimulation of the ear. The evidence on
electromagnetic energy includes a small RCT, which found no benefit for the treatment of tinnitus. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have tinnitus who receive transmeatal laser irradiation, the evidence includes RCTs and crossover trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence for transmeatal laser irradiation includes a number of double-blind RCTs, most of which showed no efficacy of this treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

**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 (e.g., 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 because, 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 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. The Heidelberg model uses an intensive program of active and receptive music therapy, relaxation with habituation to the tinnitus sound, and stress mapping with a therapist.
Sound therapy is a treatment approach based on evidence of auditory cortex reorganization (cortical remapping) with tinnitus, hearing loss, and sound/frequency training. One type of sound therapy uses an ear-worn device (Neuromonics Tinnitus Treatment; 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 uses music with the frequency of the tinnitus removed (notched music) to promote reorganization of sound processing in the auditory cortex. One theory behind notched music is that tinnitus is triggered by injury to inner ear hair cell population, resulting in both a loss of excitatory stimulation of the represented auditory cortex and loss of inhibition on the adjoining frequency areas. It is proposed that this loss of inhibition leads to hyperactivity and overrepresentation at the edge of the damaged frequency areas and that removing the frequencies overrepresented at the audiometric edge will result in reorganization of the brain.

Electrical stimulation to the external ear has also been investigated and is based on the observation that electrical stimulation of the cochlea associated with a cochlear implant may be associated with a reduction in tinnitus. Transcranial magnetic stimulation, electrical stimulation, and transmeatal low-power laser irradiation have also been evaluated.

**Regulatory Status**
The Neuromonics® Tinnitus Treatment is one of many tinnitus maskers 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.

**Rationale**
This evidence review was created in August 2001 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through December 11, 2017.

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

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

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.(1) Treatments evaluated included laser, transcranial magnetic stimulation, hyperbaric oxygen therapy, sound treatments, and psychological/behavioral treatments. Studies met inclusion criteria if they had a comparator or control treatment, which could include placebo, no treatment, waiting list, treatment as usual, or other intervention. Eleven studies selected focused on medical interventions, 4 on sound technology interventions, and 19 on psychological and behavioral interventions. Reviewers found insufficient evidence for medical and sound technology interventions. For psychological and behavioral interventions, there was low 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 (QOL). Evidence was insufficient for other psychological and behavioral interventions such as tinnitus retraining therapy and relaxation.

PSYCHOLOGICAL COPING THERAPY
A 2010 Cochrane review included 8 trials with a total of 468 participants (see Table 1).(2) Inclusion criteria for all but 1 trial included presence of symptoms for at least 6 months and subjective impairment or annoyance. The experimental groups included CBT, self-help CBT, tinnitus coping therapy (TCT), psychophysiological treatment, and biofeedback. There were no significant differences in subjective tinnitus loudness between psychological therapies and either no treatment or another intervention, but there was an improvement in QOL associated with decreased global tinnitus severity. The analysis found evidence that depression scores improved when comparing CBT with no treatment, but there was no evidence of benefit in depression scores when compared with other treatments (yoga, education, minimal contact education).
Table 1. Characteristics of a Meta-Analysis of RCTs

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

Adapted from Martinez-Devesa et al (2010).2 CBT: cognitive-behavioral therapy; RCT: randomized controlled trial; TCT: tinnitus coping therapy; TRQ: Tinnitus Reaction Questionnaire; TQ: Tinnitus Questionnaire.

**Cognitive-Behavioral Therapy**

Zenner et al (2013) reported on a multicenter pragmatic trial of a standardized, individual, tinnitus-specific CBT program vs a waiting-list control in 286 patients between 14 and 78 years of age.(3) Four sites enrolled patients into the CBT program, while a fifth site enrolled patients into the waiting-list control group. There were differences between groups at baseline for tinnitus compensation, tinnitus quality, and tinnitus duration. 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 of 3.4 (95% confidence interval [CI], 2.6 to 4.5) in intention-to-treat (ITT) 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 than in the control group. The TQ is a validated, 52-item self-rating scale that assesses emotional and cognitive distress, intrusiveness, auditory perceptual difficulties, sleep disturbance, and somatic complaints. Tinnitus change, loudness, and annoyance scales appear to have been developed and tested for validity in a prior study by the authors of this report.

**Acceptance and Commitment Therapy**

Westin et al (2011) reported on an RCT of acceptance and commitment therapy (ACT) vs tinnitus retraining therapy or waiting-list control in 64 patients with normal hearing.(4) 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 scores improved from 45.27 at baseline to 28.19 at
18 months. In the tinnitus retraining group, THI score improved from 47.00 at baseline to 41.86 at 18 months, while the waiting-list control was unchanged at 48.29. THI scores were significantly improved in the ACT group (54.5%) compared with the tinnitus retraining group (20%; p<0.04).

**Self-Help and Internet-Based Coping Therapies**

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

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

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). Both CBT interventions resulted in significant improvements in the primary outcome measures of the THI and Mini-Tinnitus Questionnaire (TQ) scores, with no significant differences between the 2 groups. A clinically relevant response on the THI, defined as a 14-point improvement, was found for 41% of the ICBT participants and 50% of the GCBT participants at the conclusion of treatment. At 6-month follow-up, the responder rate was 49% for ICBT and 51% for GCBT. Responder analysis was not reported for the control group. The amount of time therapists spent with each patient was similar for both CBT groups, with an average of 11 messages sent and 9 received in the ICBT group and an average of 10 participants in each 90-minute weekly session for GCBT. A greater percentage of patients considered GCBT to be more effective than ICBT, and more GCBT patients were satisfied with their treatment.

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

Beukes et al (2017) randomized (1:1) 146 individuals with tinnitus to 8 weeks of Internet-based cognitive behavior therapy guided by an audiologist or to a control group, which received the therapy after the experimental group. Among several assessment measures given to the groups (which included a number of questionnaires), the primary measure of interest was the Tinnitus Functional Index (TFI) score. At baseline, the mean TFI score was similar between experimental and control groups (respectively, 59.8 and 59.2); given a clinically significant reduction of 23.3 points, over half of the experimental group (51%) experienced such a reduction, compared with 5% of the control group following the initial 8 weeks of the study. Secondary measures were assessed by the following questionnaires: Insomnia Severity Index, Patient Health Questionnaire, Hyperacusis Questionnaire, Cognitive Failures Questionnaire, Satisfaction with Life Scales, Generalized Anxiety Disorder, and Hearing Handicap Inventory for Adults Screening version. For all but the last 2 measures listed (anxiety and hearing disability), significant improvements were observed for varying percentages of the experiment group, especially from the fourth week of treatment to its end. The authors acknowledged several limitations, among them the lack of data regarding treatment credibility and the inclusion of several questionnaires that potentially are not proven psychometrically. Also, the patients were not identified in a clinical setting, but responded to a general call for participants with tinnitus; finally, only 73% of the experimental group and 82% of the control group remained to the study’s completion at 2 months. Despite these limitations, the authors noted the sustained improvements in tinnitus-related symptoms following internet-based CBT.

Also employing the TFI, Henry et al (2017) sought to determine the relative efficacy of several different types of hearing aid devices (all manufactured by Phonak) as worn by persons with tinnitus. Fifty-five participants were randomized and instructed to bilaterally wear the devices for 4 months: extended-wear hearing aids (EWHA [n=18]), traditional receiver-in-the-canal hearing aids (HA [n=18]), and receiver-in-the-canal hearing aids with a sound generator (HA+SG [n=19]). Most participants experienced their tinnitus symptoms reduce. Clinically significant improvement was noted in all of the groups: 67% saw improvement in the HA set, 79% in HA+SG, and 82% in the HA set. Improvement was measured by a 13-point reduction in TFI score. On average, for each of the sets: 21 points were shaved down in the HA set; 31 points in the EWHA set, and 33 points in the HA+SG set. While these reductions are noteworthy and while each
of the devices did provide relief to those suffering with tinnitus, no single hearing aid device proved to be better than the other at a statistically significant level.

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

SOUND THERAPY

Tinnitus Masking
A 2010 Cochrane review, with an update in 2012, evaluated the evidence for masking in the management of tinnitus in adults.(11,12) 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. Reviewers concluded that, due to the lack of quality research and the common use of combined approaches (hearing therapy plus counseling), the limited data failed to show evidence of the efficacy of masking therapy in tinnitus management. A 2015 study of preferences for hearing aids and tinnitus maskers 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.(13)

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

Neuromonics Tinnitus Treatment
A 2008 industry-sponsored randomized study compared treatment with a proprietary customized acoustic stimulus for tinnitus retraining or counseling alone.(14) Fifty (of 88 subjects recruited) were found to meet the inclusion and exclusion criteria. Mean length of time that tinnitus bothered patients was 3.6 years (range, 0.2-23 years). Patients were allocated to 1 of 4 groups, (1) customized acoustic stimulus at high intensity for 2 hours a day, (2) customized acoustic stimulus at a lower intensity, (3) tinnitus retraining therapy with a broadband stimulator and counseling, or (4) counseling alone. Subjects were instructed to listen to the devices for 2 hours a day at the time of day when
symptoms were most severe and at a level that completely (group 1) or partially (group 2) masked the tinnitus; 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 groups). All patients lost to follow-up were included in the dataset for analysis using the last value carried forward method. Mean scores on the TRQ improved for the combined customized acoustic stimuli group over the 12 months of the study. TRQ scores did not improve significantly in the control groups. At 6-month follow-up, 86% of patients in the combined acoustic stimuli group had met the definition of success based on 40% improvement in TRQ scores. Normalized visual analog scale (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 acoustic device described results for the first 552 patients who received treatment at specialized clinics in Australia.(15) 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, TRQ scores improved (>40%) in 92% of tier 1 patients, in 60% of tier 2 patients, and in 39% of tier 3 patients. Investigators did not report whether the reduction in symptoms persisted when treatment stopped. Controlled studies with long-term follow-up would be needed to evaluate the durability of treatment and the relative contribution to these results of generalized masking vs desensitization.

**Auditory Discrimination Training**

Herraiz et al (2010) randomized 45 patients who scored mild or moderate (<56) on the THI to auditory discrimination training with the same frequency as the tinnitus pitch (SAME) or training on a frequency near to but not the same as the tinnitus pitch (NONSAME).(16) An additional 26 patients were included in a waiting-list control group. Auditory discrimination consisted of 20 minutes of training every day for 30 days, during which the patient had to record whether each stimulus pair was the same or different. Forty-one (91%) patients completed training and follow-up questionnaires. Four percent of patients in the waiting-list control group reported their tinnitus to be better compared with 42% of patients in the auditory discrimination training group. Self-reported improvement in tinnitus tended to be greater in the NONSAME group (54%) compared with the SAME group (26%), although subjective improvement was variable, and the difference did not statistically significant. 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 in patients trained on SAME frequencies (2.11; p=0.035).

**Notched Music**
In another 2010 publication, Okamato et al reported on 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.(17) An additional group of patients, unable to participate in the music training due to time constraints, served as a monitoring control. Thirty-nine patients who met the strict 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 (≈12 h/wk), there was a significant decrease in tinnitus loudness (≈30%) in the target-notched music group but not in the placebo or monitoring groups. Evoked activity to the tinnitus frequency, measured by magnetoencephalography, was also reduced in the primary auditory cortex of the target music group but not in the placebo or monitoring groups. Change in subjective tinnitus loudness and auditory-evoked response ratio correlated (r=0.69), suggesting an association between tinnitus loudness and reorganization of neural activity in the primary auditory cortex. Additional studies with a larger number of patients would be needed to evaluate this novel and practical treatment approach.

Stein et al (2016) reported on a double-blinded and adequately powered RCT of notched music training in 100 participants with tonal tinnitus.(18) There was no restriction for age or magnitude of hearing loss, and randomization was stratified for these factors. Participants provided their preferred music and were advised to listen for 2 successive hours a day for 3 months. The active treatment removed one half octave around the tinnitus frequency, while amplifying the edge frequency bands by 20 dB. The placebo treatment consisted of music with a moving notch. The primary outcomes were tinnitus perception (loudness, annoyance, awareness, handicap) measured with total VAS scores and tinnitus distress on the THQ. No effect was found for the primary outcome measures by either ITT or per protocol analysis, although the subscale of tinnitus loudness was reported to be reduced.

**Sound Options Tinnitus Treatments**
Li et al (2016) reported on a double-blinded randomized evaluation of 12 months of at least 2 hours daily of classical music that was spectrally altered according to a proprietary computational model of the individual’s auditory threshold and tinnitus characteristics (eg, tonal, ringing, hissing, primary frequency).(19) Controls listened to unaltered classical music for the same period of time, and both groups were assessed at baseline and 2, 6, and 12 months after initial testing. The trial had high loss to follow-up and was insufficiently powered, with only 34 (68%) of 50 patients completing the study. Three individuals dropped out before the baseline session, 4 dropped out during follow-up, and 9 were excluded due to noncompliance with the study requirements, which may have been related to the limited (6-hour) selection of music. At 12 months, the difference between groups, controlling for baseline score and treatment adherence, was -17.41 on the THI.
(p=0.001), with an effect size of 0.60. The percentage of participants who were at least moderately handicapped by tinnitus (THI score ≥38) decreased from 60% to 33% in the treated group but remained unchanged (at 63% in the control group. Scores did not differ significantly between groups for Tinnitus Functional Index (TFI) or HADS scores. Interpretation of this study is limited by the high dropout and noncompliance rates.

**Section Summary: Sound Therapy**

Sound therapies include tinnitus masking and customized sound therapy. The evidence on tinnitus masking includes a number of RCTs and a systematic review. The RCTs, which have medium-to-high risk of bias, have not shown evidence of efficacy of masking therapy. Customized sound therapy has a solid neurophysiologic basis and the potential to substantially improve tinnitus symptoms; however, research in this area appears to be at an early stage. For example, the studies described use very different approaches for sound therapy, and it is not yet clear whether therapy is more effective when the training frequency is the same or adjacent to the tinnitus pitch, or when it is altered based on the tinnitus characteristics. A 2016 trial, double-blinded and adequately powered, found no benefit of notched music on the primary outcome measures of tinnitus perception and tinnitus distress, although the subcomponent score of tinnitus loudness was reported to be reduced. A benefit on tinnitus loudness but not tinnitus perception or tinnitus distress is unusual, and would need to be corroborated in additional studies.

**COMBINED PSYCHOLOGICAL AND SOUND THERAPY**

**Tinnitus Retraining Therapy**

A 2011 systematic review identified 3 RCTs using tinnitus retraining therapy.(20) One trial did not find an improvement over an education-only intervention, and 2 provided low-quality evidence for the efficacy of an individualized multicomponent intervention that included tinnitus retraining. Additional controlled studies are described next.

The 2011 RCT by Westin (previously described) compared results of tinnitus retraining with ACT or waiting-list control in 64 patients with normal hearing.(4) In this trial, tinnitus retraining was significantly less effective than ACT. The percentage of patients with reliable improvements was 54.5% in the ACT group and 20% in the tinnitus retraining group (p<0.04), with 10% of patients in the tinnitus retraining group showing deterioration over the course of the trial. In the tinnitus retraining group, THI scores improved from 47.00 at baseline to 41.86 at 18 months, while waiting-list control score was unchanged at 48.29. Interpretation of these findings is limited by the lack of a placebo-control group.

Bauer and Brozoski (2011) reported on a pseudorandomized study of tinnitus retraining therapy in 32 patients with normal to near-normal hearing (75% follow-up).(21) Group assignment was balanced by tinnitus severity on the THI, Beck Depression Inventory scores, and sex. Participants were assigned to 8 hours of daily tinnitus retraining with three 1-hour sessions of individual counseling on
tinnitus retraining over 18 months, or a control arm of 3 counseling sessions that included coping techniques and sham sound therapy. Participants in the control arm were provided with a sound device and told to increase use to 8 hours a day, although the device ramped to off in 30 minutes. Participants were evaluated at 6, 12, and 18 months with a computerized test battery of questionnaires and psychophysical procedures. The primary outcome measure was THI score. Secondary outcome measures were change in global tinnitus impact, subjective tinnitus loudness rating, and objective tinnitus loudness measured by a psychophysical matching procedure. THI score improved over the 18 months to a similar extent for both the active and sham tinnitus retraining therapy groups. Subjective loudness was significantly reduced in the tinnitus retraining group compared with controls at 12 and 18 months (p=0.04), but there were no between-group differences in the rating of annoyance and distress.

Another pseudorandomized trial from a Veterans Administration medical center, published in 2006, compared tinnitus masking and tinnitus retraining therapy.(22) Following initial screening for tinnitus severity and motivation to comply with the 18-month study, 59 subjects were enrolled in the tinnitus-masking condition (mean age, 61 years), and 64 were enrolled in tinnitus retraining (mean age, 59 years). Treatment included appointments with tinnitus specialists at 3, 6, 12, and 18 months to check the ear-level devices and to receive the group-specific counseling (about 4-5 hours total). At each visit, the subjects completed the THI, Tinnitus Handicap Questionnaire, and Tinnitus Severity Index, and underwent tinnitus and audiologic tests. Questionnaire results showed minor-to-modest improvement at the 3- and 6-month follow-ups for both treatment groups, favoring slightly the masking condition. After 12 months of treatment, medium effect sizes (0.57-0.66) were reached for the tinnitus retraining group and, after 18 months of treatment, major effect sizes (0.77-1.26) were obtained. It was noted by the authors that several confounding variables were present in this study, including differences in counseling between the 2 groups. The 2006 trial is the only trial that met selection criteria for a 2010 Cochrane review(23) and a 2014 systematic review by Grewal et al.(24)

Heidelberg Neuromusic Therapy
Argstatter et al (2015) reported on a 2-center, investigator-blinded RCT with 290 patients treated with neuromusic therapy or a single counseling session.(25) Therapy was provided in eight 50-minute sessions, with 2 sessions a day. Each session consisted of 25 minutes of receptive (music-listening based) and 25 minutes of active (music-making) therapy. Active music therapy included resonance training and intonation training. The receptive music component offered coping mechanisms related to stress control along with a sound-based habituation procedure. Patients in both groups received a 50-minute individualized counseling session. The primary outcome was the change in TQ scores by ITT 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 counseling). Both groups improved over time, with a greater reduction in TQ scores for music therapy (median, 11.2 points vs 2.3 points). Clinically significant improvements were obtained in 66% of music therapy patients compared with 33% of patients in the active control group.
Multidisciplinary Therapy
Cima et al (2012) reported on a large RCT of usual care vs a combination of approaches.(26) 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 [ES], 0.24), decrease in tinnitus severity (ES=0.43), and decrease in tinnitus impairment (ES=0.45).

Section Summary: Combined Psychological and Sound Therapy
The evidence on tinnitus retraining therapy consists of a number of small randomized or quasi-randomized controlled trials. Together, the literature does not show consistent improvement in the primary outcome measure (THI score) when tinnitus retraining therapy is compared with active or sham controls. For Heidelberg neuromusic therapy there is 1 study that used an investigator-blinded RCT design and showed positive short-term results following treatment. The durability of treatment is also unknown. A multidisciplinary therapy was shown to improve outcomes in a large RCT, but because the specialized care protocol was an intensive, multidisciplinary intervention, it is uncertain which of its components were associated with improvements in outcomes. It is also uncertain whether such an intensive treatment could be provided outside of the investigational setting.

REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION
Soleimani et al (2016) published a systematic review of 15 double-blind randomized trials with sham controls on repetitive transcranial magnetic stimulation (rTMS).(27) Seven of these trials were included in a meta-analysis. The primary outcomes were the mean THI and TQ scores. The secondary outcomes of therapeutic success were defined as a reduction of 7 points on the THI (maximum, 100) or 5 points on the TQ (maximum, 84), but the percentage of patients who achieved therapeutic success was not reported. Mean difference in TQ scores at 1 week after treatment was 3.42 (4 studies). Mean difference in THI scores between the TMS and sham groups was 6.71 at 1 month after treatment (4 studies, p<0.001) and 12.89 at 6 months after treatment (3 studies, p<0.001). The odds ratio at 1 month after treatment was 15.75 (p=0.004), although the sample size was small in the 3 included studies (range, 8-20 patients). A qualitative review of the 15 trials found significant benefit of rTMS in 9 and no significant effect in 6. There was significant heterogeneity in the population, target brain area, stimulation parameters, and length of follow-up.

The largest study included in the 2016 systematic review is that by Langguth et al (2014).(28) 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 neuro-navigated rTMS (n=48), rTMS over the left auditory cortex (n=48), or rTMS over both the left auditory cortex and left frontal cortex (n=48). The sham group (n=48) ran concurrently with the navigated rTMS group (between 2004 and 2006) while the other 2 groups ran concurrently between 2007 and 2009. There were no significant differences in mean TQ scores between groups, and no significant difference between groups in improvements in TQ scores over time. The percentage of treatment responders was significantly higher for left temporal rTMS (38%) and combined frontal and temporal rTMS (43%) compared with sham (6%). However, interpretation of these results is limited by the nonconcurrent sham controls.

Folmer et al (2015) published results from a double-blind sham-controlled randomized trial with 70 patients.(29) Patients received 10 days of rTMS, and had follow-up assessments at 1, 2, 4, 13, and 26 weeks after the last treatment session. Sixty-four patients were included in data analysis. Primary outcomes were change from baseline as measured by the TFI score and percentage of responders measured by a 7-point improvement in TFI score. There were significant differences between groups in change from baseline at weeks 1, 2, and 26, but not at weeks 4 and 13. There was a significantly higher percentage of responders following active rTMS compared with sham TMS immediately after treatment (56% vs 22%, p<0.005) and at 26 weeks (66% vs 38%), but not at weeks 1, 4, or 13. The benefit of rTMS increased over the 26 weeks of the trial, with a change in the mean TFI score of -5.2 immediately after treatment, increasing to -13.8 at 26 weeks. Additional study would be needed to corroborate these results and to evaluate the durability of the treatment.

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

ELECTRICAL AND ELECTROMAGNETIC STIMULATION

Transcranial Direct Current Stimulation
Song et al (2012) published a systematic review of transcranial direct current stimulation (tDCS) for the treatment of tinnitus.(30) 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 RCTs showed a medium-to-large effect size of 0.77. In 2015, Pal et al reported on a trial involving 42 patients randomized to 5 days of sham stimulation or tDCS over the frontal and auditory cortices.(31) They found no beneficial effect of tDCS on the primary (THI score) or secondary outcome measures in this adequately powered double-blind study.
In a meta-analysis performed by Wang et al (2017), the aim was to look at the impact of tDCS on patients suffering with tinnitus. A number of studies were surveyed, and each one needed to have recorded certain outcomes as it pertained to tDCS: loudness (as observed by change in magnitude), distress as suffered by those with tinnitus, and scores from the Tinnitus Handicap Inventory (THI). The results were the following: there was no observable benefit to tDCS when it came to hearing loudness (pooled standardized difference in means [PSDIM], 0.671; 95 CI, -0.089 to 1.437; p=0.83); tinnitus-related distress decreased for those using tDCS (PSDIM=0.634; 95% CI, 0.021 to 1.247; p=.043). Only 3 studies dealt with changes in THI; however, no statistical heterogeneity could be determined. While the reduction in tinnitus-related distress is notable in this meta-analysis, further study is needed to evaluate tDCS as a treatment option for those suffering with tinnitus.

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

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

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

Section Summary: Electrical and Electromagnetic Stimulation
The evidence on electrical and electromagnetic stimulation for the treatment of tinnitus includes sham-controlled randomized trials. The available evidence does not currently support use of these treatments. A 2015 study, sham-controlled and adequately powered, found no benefit of tDCS. Studies have not shown a benefit for direct current electrical stimulation of the ear. The evidence on electromagnetic energy includes a small RCT that found no benefit for the treatment of tinnitus.
TRANSMEATAL LASER IRRADIATION
A number of randomized double-blind placebo-controlled trials have examined transmeatal low-level laser therapy. Most were conducted outside of the United States and showed no efficacy. For example, transmeatal low-level laser was not more effective than placebo in a double-blind RCT with 60 patients from 2002,(37) in a 2009 placebo-controlled, double-blind randomized trial with 60 patients,(38) a 2014 placebo-controlled, double-blind randomized trial with 48 patients,(39) or a 2015 placebo-controlled, double-blind randomized trial with 66 patients.(40)

Section Summary: Transmeatal Laser Irradiation
The evidence on transmeatal laser irradiation includes a number of double-blind RCTs, most of which showed no efficacy of this treatment.

SUMMARY OF EVIDENCE
Overwrite with Summary.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

European Chapter of the International Federation of Clinical Neurophysiology
The European Chapter of the International Federation of Clinical Neurophysiology sponsored evidence-based guidelines for the use of transcranial direct current stimulation (tDCS).(41) The consensus group did not recommend tDCS as a treatment for tinnitus, as studies suggested anodal tDCS of the left temporoparietal cortex was probably ineffective (level B evidence). A lack of data precluded any recommendation of tDCS of the left dorsolateral prefrontal cortex as therapy for chronic tinnitus.

American Academy of Otolaryngology – Head and Neck Surgeons
In 2014 the American Academy of Otolaryngology – Head and Neck Surgeons published evidence-based guidelines on tinnitus.(42) The guidelines included the following recommendations:

- 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.

MEDICARE NATIONAL COVERAGE
The Centers for Medicare and Medicaid Services had a longstanding national coverage determination for tinnitus masking, which was considered an experimental therapy because of the lack of controlled clinical trials demonstrating effectiveness and the unstudied possibility of serious toxicity in the form of noise-induced hearing loss. The national coverage determination was retired in 2014. (43)

ONGOING AND UNPUBLISHED CLINICAL TRIALS
Some ongoing trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
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<tr>
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<td></td>
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<tr>
<td>NCT03068871</td>
<td>A Comparison of Two Psycho-educational Group Interventions for Tinnitus Patients</td>
<td>60</td>
<td>May 2017 (ongoing)</td>
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<td>NCT02370810</td>
<td>Study Protocol for a CBT-based Internet Intervention for Adults With Tinnitus in the United Kingdom: A Randomised Controlled Trial</td>
<td>160</td>
<td>Sep 2017 (ongoing)</td>
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<tr>
<td>NCT02665975</td>
<td>Internet-based Versus Face-to-face Clinical Care for Tinnitus: A Multi-study Randomised Control Trial</td>
<td>80</td>
<td>Nov 2017 (ongoing)</td>
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<td>NCT02653547</td>
<td>Influence of Treatment Duration and Stimulation Frequency on Repetitive Transcranial Magnetic Stimulation in Chronic Tinnitus</td>
<td>80</td>
<td>Jul 2017 (ongoing)</td>
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<td>NCT02438891</td>
<td>Evaluation of an Internet-based Sound and Treatment of Tinnitus 8.01.39</td>
<td>200</td>
<td>Jul 2018</td>
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<tr>
<td>Trial ID</td>
<td>Title</td>
<td>NCT</td>
<td>Start Date</td>
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<tr>
<td>NCT03026829a</td>
<td>&quot;Cochlear Active Relief From Tinnitus (CART) Sound Therapy&quot; for Tinnitus Relief in Nucleus® Cochlear Implant Users With Tinnitus</td>
<td>50</td>
<td>Jul 2018</td>
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<td>NCT02794623</td>
<td>Evaluation of Tinnitus Suppression for Cochlear Implant Recipients</td>
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<td>Aug 2019</td>
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<tr>
<td>NCT03022084</td>
<td>Clinical Trial of Sound-Based Versus Behavioral Therapy for Tinnitus</td>
<td>200</td>
<td>Dec 2019</td>
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<td>NCT03114878</td>
<td>The Value of Eye Movement Desensitization Reprocessing in the Treatment of Tinnitus</td>
<td>166</td>
<td>Dec 2019</td>
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<tr>
<td>NCT02071732</td>
<td>Repetitive Transcranial Magnetic Stimulation (rTMS) Effect on Tinnitus</td>
<td>40</td>
<td>Dec 2019</td>
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<td>NCT00926237</td>
<td>Effect of rTMS on Resting State Brain Activity in Tinnitus</td>
<td>60</td>
<td>Sep 2020</td>
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<tr>
<td><strong>Unpublished</strong></td>
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<tr>
<td>NCT02408575</td>
<td>Hearing Aids With &quot;Notched Amplification&quot; for the Treatment of Chronic Tinnitus - A Controlled Randomized Pilot Study on Safety, Tolerability and Clinical Performance</td>
<td>44</td>
<td>Jun 2016</td>
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<tr>
<td>NCT01929837</td>
<td>Treatment of Tinnitus With Transcranial Magnetic Stimulation</td>
<td>80</td>
<td>Aug 2016</td>
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<tr>
<td>NCT02293512</td>
<td>A Comparison of CBT and CET Interventions for Veterans With Tinnitus</td>
<td>80</td>
<td>Nov 2016</td>
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<tr>
<td>NCT01177137</td>
<td>Tinnitus Retraining Therapy Trial</td>
<td>228</td>
<td>Feb 2017</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
a Denotes industry-sponsored or co-sponsored trial.

References:


**Billing Coding/Physician Documentation Information**

There is no specific CPT code for psychological coping therapy. The CPT codes used may include evaluation and management codes or possibly 96152 (health and behavior intervention, each 15 minutes, face-to-face, individual) or an unlisted code depending on the type of service and provider.

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 (application of a modality to one or more areas; electrical stimulation) or speech therapy (92507). As tinnitus-retraining therapy in part involves counseling, an individual psychotherapy CPT code may be used (code range 90804-90809). 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 (application of a modality; infrared), 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 (transcutaneous electrical nerve stimulation, two-lead, localized stimulation).

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)

<table>
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<td>S8948</td>
<td>Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes</td>
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ICD-10-CM

<table>
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<td>Tinnitus code range</td>
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**Policy Implementation/Update Information**

9/1/08  New policy; considered investigational.

9/1/09  No policy statement changes.

9/1/10  Policy statement revised to list tinnitus coping therapy, transcutaneous electrical stimulation, and sound therapy as investigational.

9/1/11  No policy statement changes.

9/1/12  No policy statement changes.

9/1/13  No policy statement changes.

9/1/14  No policy statement changes.

9/1/15  No policy statement changes. Added additional coding info for CPT 97026 and S8948.

9/1/16  Policy statement reordered and “surgical” added to the note on topics that the policy does not address.

4/1/17  Psychological coping therapy may be considered medically necessary for persistent and bothersome tinnitus. Combined psychological and sound therapy added to the investigational policy statement. Botulinum toxin type A injections were removed from the investigational statement as they are addressed in a separate policy (botulinum toxin).

9/1/17  No policy statement changes.

4/1/18  The medically necessary statement revised to define psychological coping therapy; biofeedback added to the investigational statement.

9/1/18  No policy statement changes.

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