Treatment of Tinnitus

Policy Number: 8.01.39  Last Review: 9/2019

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 (eg 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 (eg, 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

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

For individuals who have persistent, bothersome tinnitus who receive psychological coping therapy, the evidence includes 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 cognitive and behavioral therapies have found improvements in global tinnitus severity and quality of life, even when tinnitus loudness is not affected. Other RCTs have reported that a self-help/Internet-based approach to cognitive and behavioral therapy or acceptance and commitment therapy may also improve coping skills. The evidence is sufficient to determine that the technology results in a meaningful improvement in health outcomes.

For individuals who have tinnitus who receive sound therapy, the evidence includes RCTs and a systematic review of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence...
on tinnitus masking includes RCTs and a systematic review of RCTs. The RCTs had medium-to-high risk of bias and did not show the efficacy of masking therapy. Research on customized sound therapy appears to be at an early stage. For example, the studies described the use of very different approaches for sound therapy, and it is not yet clear whether therapy is more effective when the training frequency is the same or adjacent to the tinnitus pitch. A 2016 trial, double-blinded and adequately powered, found no benefit of notched music on the primary outcome measures of tinnitus perception and tinnitus distress, although the subcomponent score of tinnitus loudness was reported to be reduced. A benefit on tinnitus loudness but not tinnitus perception or tinnitus distress is of uncertain clinical significance, may be spurious, and would need corroboration in additional studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have tinnitus who receive combined psychological and sound therapy, 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-RCTs. Collectively, the literature does not show consistent improvements in the primary outcome measure (Tinnitus Handicap Inventory scores) when tinnitus retraining therapy is compared with active or sham controls. For Heidelberg neuromusic therapy, a trial has used an investigator-blinded RCT design and showed positive short-term results following treatment. However, the durability of treatment is also unknown. A large, multicenter RCT trial using an intensive, multidisciplinary intervention showed improvement in outcomes. However, it is uncertain whether the multiple intensive interventions used in this trial could be replicated outside of the investigational setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals who have tinnitus who receive electrical or electromagnetic stimulation, the evidence includes a number of sham-controlled randomized trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The available evidence does not currently support the use of these stimulation therapies. A 2015 sham-controlled study that was adequately powered found no benefit of transcranial direct current stimulation. Moreover, while a 2017 meta-analysis found some benefit for transcranial direct current stimulation, it was noted that further study would be needed to evaluate transcranial direct current stimulation 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 treatment efficacy. 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.

**Table 1. Devices Cleared by the US Food and Drug Administration**

<table>
<thead>
<tr>
<th>Devices</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
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<tr>
<td>Tinnitus Sound Generator Module</td>
<td>Gn Hearing A/S</td>
<td>11/30/2018</td>
<td>K180495</td>
<td>Tinnitus Relief</td>
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<td>Audifon Tinnitus-Module</td>
<td>Audiofon Usa Inc.</td>
<td>10/19/2017</td>
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<td>Tinnilogic Mobile Tinnitus Management De</td>
<td>Jiangsu Betterlife Medical Co., Ltd.</td>
<td>5/17/2017</td>
<td>K163094</td>
<td>Tinnitus Relief</td>
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### Treatment of Tinnitus 8.01.39

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Manufacturer</th>
<th>Date</th>
<th>Evidence ID</th>
<th>Type of Relief</th>
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<td>Sound Options Tinnitus Treatments Inc.</td>
<td>9/28/2016</td>
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<td>Hypersound Tinnitus Module</td>
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<td>Desyncra For Tinnitus Therapy System, De</td>
<td>Neurotherapies Reset GmbH.</td>
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<td>Reve134</td>
<td>Kw Ear Lab, Inc</td>
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<td>Serenity</td>
<td>Sanuthera, Inc.</td>
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<td>Soundcure Serenade Tinnitus Treatment Sy</td>
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<td>Levo Tinnitus Masking Software Device</td>
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<td>Solace Sound Generators</td>
<td>Amplisound Hearing Products &amp; Services</td>
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<td>Wave 2g, Soul</td>
<td>Hansaton Akustik GmbH</td>
<td>1/3/2014</td>
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</table>

### 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 January 11, 2019.

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.

**Tinnitus Treatment Overview**

In 2013, the Agency for Healthcare Research and Quality published a comparative effectiveness review on assessment and treatment of tinnitus. 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-level evidence for an effect of cognitive-behavioral therapy (CBT) on tinnitus-specific quality of life (QOL), and low-level evidence for no effect of CBT on subjective loudness, sleep disturbance, anxiety, depression, and global QOL. Evidence was insufficient for other psychological and behavioral interventions such as tinnitus retraining therapy and relaxation.

**Psychological Coping Therapy For the treatment of tinnitus**

**Clinical Context and Test Purpose**

The purpose of Psychological coping therapy is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard therapy, in patients with persistent, bothersome tinnitus.

The question addressed in this evidence review is: does nonpharmacologic therapy such as psychological coping therapy improve the net health outcome for patients with tinnitus?

The following PICOTS were used to select literature to inform this review.
Patients
The relevant population of interest are individuals with persistent, bothersome tinnitus.

Interventions
The therapy being considered is psychological coping therapy.

Comparators
Comparators of interest include standard therapy including stress management and noise suppression therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Timing
The existing literature evaluating psychological coping therapy as a treatment for persistent, bothersome tinnitus has varying lengths of follow up, ranging from 6 months to 1 year. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 1 year of follow-up is considered necessary to demonstrate efficacy.

Setting
Patients with persistent, bothersome tinnitus are actively managed by otolaryngologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

A 2010 Cochrane review included 8 trials with a total of 468 participants (see Table 1). Inclusion criteria for all but 1 trial included the presence of symptoms for at least 6 months and subjective impairment or annoyance. The experimental groups included CBT, self-help CBT, tinnitus coping therapy, 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 2. Characteristics of a Meta-Analysis of Randomized Controlled Trials

<table>
<thead>
<tr>
<th>Study</th>
<th>Groups</th>
<th>N</th>
<th>Inclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andersson et al (2005)</td>
<td>CBT, waitlist</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Henry et al (1996)</td>
<td>CBT, education, waitlist</td>
<td>60</td>
<td>≥17 points on TRQ</td>
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<tr>
<td>Kaldo et al (2007)</td>
<td>Self-help CBT, waitlist</td>
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<td>≥10 points on TRQ</td>
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<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>
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<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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<td>Rief et al (2005)</td>
<td>Psychophysiological, waitlist</td>
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<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>
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</tbody>
</table>

Adapted from Martinez-Devesa et al (2010).<sup>2</sup>
CBT: cognitive-behavioral therapy; TCT: tinnitus coping therapy; TQ: Tinnitus Questionnaire; TRQ: Tinnitus Reaction Questionnaire.

Table 3. SR & M-A Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Improvement on QOL</th>
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</thead>
<tbody>
<tr>
<td>Henry 1995</td>
<td>N=20</td>
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<tr>
<td>Treatment</td>
<td>N=20</td>
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<td>Mean(SD)</td>
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<tr>
<td>Control</td>
<td>N=20</td>
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<tr>
<td>Study</td>
<td>Group</td>
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<tr>
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<td>Weise et al (2008)</td>
<td>Treatment</td>
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<td></td>
<td>Mean (SD)</td>
</tr>
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</table>
Cognitive-Behavioral Therapy

McKenna et al (2018) published the results of their study that describes the impact of mindfulness-based cognitive therapy (MBCT) in a “real world” tinnitus clinic, using standardized MBCT on the largest sample of patients (n=182) with chronic tinnitus to date. Participants were adults with chronic and distressing tinnitus who completed an 8-week MBCT group. Measures of tinnitus-related distress, psychological distress, tinnitus acceptance, and mindfulness were taken at baseline, postintervention, and at 6-week follow-up. MBCT was associated with significant improvements on all outcome measures. Postintervention, reliable improvements were detected in tinnitus-related distress in 50% (n=91) and in psychological distress in 41.2% (n=75) of patients.

Zenner et al (2013) reported on a multicenter pragmatic trial comparing a standardized, individual, tinnitus-specific CBT program with a waiting-list control in 286 patients between 14 and 78 years of age. Four sites enrolled patients into the CBT program, while a fifth site enrolled patients into the waiting-list control group. There were differences between groups at baseline for tinnitus compensation, tinnitus quality, and tinnitus duration. Also, 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 (odds ratio, 3.4; 95% confidence interval [CI], 2.6 to 4.5) in intention-to-treat analysis. Improvement in the tinnitus change score by 2 or more points was reported by 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 comparing acceptance and commitment therapy (ACT) with tinnitus retraining therapy or waiting-list control in 64 patients with normal hearing.5 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.6 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.7

These RCTs were followed by a 2012 RCT of Internet-based CBT or ACT.8 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.

An RCT by Jasper et al (2014) 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).9 Both CBT interventions resulted in significant improvements in the primary outcome measures of THI and Mini-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. A 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 a moderated online discussion forum. For the primary outcome of tinnitus-related distress, there was a significant interaction of time by a group that was supported by large effect sizes (THI standardized effect size, 0.83; 95% CI, 0.47 to 1.20; TQ standardized effect size, 1.08; 95% CI, 0.71 to 1.64). For the secondary outcomes, Hospital Anxiety and Depression Scale, Tinnitus Acceptance Questionnaire, and Insomnia Severity Index, small-to-medium effect sizes (ES) 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 the experimental (59.8) and control (59.2) groups; 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 scale, 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 without psychometric validation. 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.
Also employing the TFI, Henry et al (2017) assessed the relative efficacy of several types of hearing aid devices (all manufactured by Phonak) worn by persons with tinnitus. Fifty-five participants were randomized and instructed to bilaterally wear the devices for 4 months: extended-wear hearing aids (n=18), traditional receiver-in-the-canal hearing aids (HA [n=18]), and receiver-in-the-canal hearing aids with a sound generator (n=19). Most participants experienced reductions in their tinnitus symptoms. Clinically significant improvement was noted in all groups: 67% saw improvement in the HA set, 79% in hearing aids with a sound generator, and 82% in the HA set. Improvement was prespecified as a 13-point reduction in TFI score. On average, the HA set reported a 21-points reduction; the extended-wear hearing aids set a 31-point reduction; and the hearing aids with a sound generator set a 33-point reduction. While each device provided tinnitus symptom relief, no single hearing aid proved statistically to be better than the other.

**Section Summary: Psychological Coping Therapy**

The evidence on the use of 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 QOL. Meta-analyses of a variety of cognitive and behavioral therapies had reported improvements in global tinnitus severity and QOL, even when tinnitus loudness was 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 for treatment of tinnitus**

**Clinical Context and Test Purpose**

The purpose of sound therapy is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard therapy, in patients with tinnitus.

The question addressed in this evidence review is: does nonpharmacologic therapies such as sound therapy improve the net health outcome for patients with tinnitus?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population of interest are individuals with tinnitus.

**Interventions**

The therapy being considered is sound therapy.
Comparators
Comparators of interest include standard therapy including stress management and noise suppression therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Timing
The existing literature evaluating sound therapy as a treatment for tinnitus has varying lengths of follow up, ranging from 6-months. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 6-months of follow-up is considered necessary to demonstrate efficacy.

Setting
Patients with tinnitus are actively managed by otolaryngologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Tinnitus Masking
A 2010 Cochrane review, updated in 2012, evaluated the evidence for masking in the management of tinnitus in adults. Selected 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 among 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.15.
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. Fiftу (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; device use 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 TRQ scores 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 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 same acoustic device described results for the first 552 patients who received treatment at specialized clinics in Australia. Patients were divided into three 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 <17), and/or moderately severe or severe hearing loss in 1 ear (>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, 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%) discontinued treatment, 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 or training on a frequency near to but not the same as the tinnitus pitch. 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 near to but not the same frequency as the tinnitus pitch group (54%) compared with the same frequency as the tinnitus pitch group (26%), although subjective improvement varied, and did not differ statistically. Subjective improvement in visual analog scale tinnitus intensity was modest and similar in both groups (0.65 vs 0.32, respectively). The decrease in THI scores was significantly greater in the patients near to but not the same as the tinnitus pitch frequencies (11.31) than in patients trained on the same as the tinnitus pitch frequencies (2.11; p=0.035).

**Notched Music**
In another publication, Okamato et al (2010) reported on a small (N=24) double-blind, pseudorandomized trial that compared 12 months of listening to notched music (with the tinnitus frequency removed) with placebo music. 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 inclusion criteria were recruited; the final group sizes after dropouts and exclusions were 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. 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 visual analog scale scores and tinnitus distress on the THQ. No effect was found for the primary outcome measures by intention-to-treat 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). 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 a 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, four dropped out during follow-up, and nine 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 scores and treatment adherence, was -17.41 on the THI (p=0.001), with an ES 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 treatment group but remained unchanged (at 63% in the control group. Scores did not differ significantly between groups for TFI or Hospital Anxiety and Depression Scale scores. Interpretation of this study was 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 a 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 subscale 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 for treatment of tinnitus

Clinical Context and Test Purpose
The purpose of combined psychological and sound therapy is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard therapy, in patients with tinnitus.

The question addressed in this evidence review is: does nonpharmacologic therapies such as combined psychological and sound therapy improve the net health outcome for patients with tinnitus?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are individuals with tinnitus.

Interventions
The therapy being considered is combined psychological and sound therapy.

Comparators
Comparators of interest include standard therapy including stress management and noise suppression therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Timing
The existing literature evaluating combined psychological and sound therapy as a treatment for tinnitus has varying lengths of follow up, ranging from [TIME]. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, a year of follow-up is considered necessary to demonstrate efficacy.

Setting
Patients with tinnitus are actively managed by otolaryngologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

d. Studies with duplicative or overlapping populations were excluded.
Tinnitus Retraining Therapy
A 2011 systematic review identified 3 RCTs evaluating tinnitus retraining therapy.\(^{22}\) One trial did not find an improvement over an education-only intervention, and two provided low-quality evidence for the efficacy of an individualized multicomponent intervention that included tinnitus retraining. Additional controlled studies are described next.

The RCT by Westin et al (2011; previously described) compared results of tinnitus retraining with ACT or waiting-list control in 64 patients with normal hearing.\(^{5}\) 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 during 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 remained 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).\(^{23}\) 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 with tinnitus retraining therapy.\(^{24}\) 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
improvements at the 3- and 6-month follow-ups for both treatment groups, slightly favoring the masking condition. After 12 months of treatment, medium ESs (0.57-0.66) were reported for the tinnitus retraining group and, after 18 months of treatment, major ESs (0.77-1.26) were obtained. Several confounding variables were reported, including differences in counseling between the 2 groups. This 2006 trial is the only trial that met selection criteria for a 2010 Cochrane review, and a systematic review by Grewal et al (2014).

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. Therapy was provided in eight sessions, 50-minutes each, 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 intention-to-treat analysis at the conclusion of the therapy. Baseline TQ scores were similar in both 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. Of the 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 QOL (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-RCTs. Collectively, the literature does not show consistent improvements in the primary outcome measure (THI score) when tinnitus retraining therapy is compared with active or sham controls. For Heidelberg neuromusic therapy, there is a 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 for treatment of tinnitus**

**Clinical Context and Test Purpose**
The purpose of repetitive transcranial magnetic stimulation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard therapy, in patients with tinnitus.

The question addressed in this evidence review is: does nonpharmacologic therapies such as repetitive transcranial magnetic stimulation improve the net health outcome for patients with tinnitus?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest are individuals with tinnitus.

**Interventions**
The therapy being considered is repetitive transcranial magnetic stimulation.

**Comparators**
Comparators of interest include standard therapy including stress management and noise suppression therapy.

**Outcomes**
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

**Timing**
The existing literature evaluating repetitive transcranial magnetic stimulation as a treatment for tinnitus has varying lengths of follow up, ranging from 1,2,3,13, and 26 weeks. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 1,2,3,13, and 26 weeks of follow-up is considered necessary to demonstrate efficacy.

**Setting**
Patients with tinnitus are actively managed by otolaryngologists and primary care providers in an outpatient clinical setting.

**Study Selection Criteria**
Methodologically credible studies were selected using the following principles:
To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs; in the absence of such trials, comparative observational studies were sought, with a preference for prospective studies. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought. Studies with duplicative or overlapping populations were excluded.

Soleimani et al (2016) published a systematic review of 15 double-blind, randomized trials with sham controls on repetitive transcranial magnetic stimulation (rTMS). Seven of these trials were included in a meta-analysis. The primary outcomes were the mean THI and TQ scores. The secondary outcomes of therapeutic success were defined as a reduction of 7 points on the THI (maximum, 100) or 5 points on the TQ (maximum, 84), but the percentage of patients who achieved therapeutic success was not reported. Mean difference in TQ scores at 1 week after treatment was 3.42 (4 studies). Mean difference in THI scores between the TMS and sham groups was 6.71 at 1 month after treatment (4 studies, p<0.001) and 12.89 at 6 months after treatment (3 studies, p<0.001). The 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). It combined data from 2 trials, in which 192 tinnitus patients were randomized to 1 of 3 different rTMS target areas or 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 differences 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. 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 as 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 than following 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 for treatment of tinnitus

Clinical Context and Test Purpose
The purpose of electrical or electromagnetic stimulation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard therapy, in patients tinnitus.

The question addressed in this evidence review is: does nonpharmacologic therapies such as electrical or electromagnetic stimulation improve the net health outcome for patients with tinnitus?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are individuals with tinnitus.

Interventions
The therapy being considered is electrical or electromagnetic stimulation.

Comparators
Comparators of interest include standard therapy including stress management and noise suppression therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Timing
The existing literature evaluating electrical or electromagnetic stimulation as a treatment for tinnitus has varying lengths of follow up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.
Setting
Patients with tinnitus are actively managed by otolaryngologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Transcranial Direct Current Stimulation
Song et al (2012) published a systematic review of transcranial direct current stimulation (tDCS) for the treatment of tinnitus.32 Six studies (3 sham-controlled randomized trials, 3 uncontrolled, open-label studies) were selected for 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 ES of 0.77. Pal et al (2015) reported on a trial involving 42 patients randomized to 5 days of sham stimulation or tDCS over the frontal and auditory cortices.33 They found no beneficial effect of tDCS on the primary (THI score) or secondary outcome measures in this adequately powered double-blind study.

A systematic review by Wang et al (2017) examined the impact of tDCS on patients with tinnitus.34 Outcomes assessed included: loudness (as observed by a change in magnitude), distress as experienced by those with tinnitus, and THI scores. The results were the following: there was no observable benefit to tDCS in reducing hearing loudness (pooled standardized difference in means, 0.671; 95 CI, -0.089 to 1.437; p=0.83); and tinnitus-related distress decreased for those using tDCS (pooled standardized difference in means, 0.634; 95% CI, 0.021 to 1.247; p=.043). Only 3 studies dealt with changes in THI scores; however, no statistical heterogeneity could be determined. While this systematic review reported a reduction in tinnitus-related distress, further study is needed to evaluate tDCS as a treatment option for tinnitus.

A randomized double-blind clinical trial with case and control groups, the results of which were published by Abtahbi et al (2018), was conducted in in Al-Zahra Hospital in Isfahan between 2015 and 2016.35 In this trial, 51 patients who had tinnitus for at least one year were selected from outpatients visiting the clinic within this period. Inclusion criteria were patients on electrical stimulation prohibition, with Ménière's disease, otosclerosis, chronic headache, and pulsatile tinnitus. Patients were randomized into one of three, equal-size arms: anodal stimulation group, cathodal stimulation group, and control group. The subjects received 20-min current stimulation (2 mA). Of those with a significant difference
between the stimulated states (anodal or cathodal) and/or control, 5 patients were selected to receive weekly transcranial electrical stimulation for 2 months, and their long-term recovery from tinnitus was investigated. The results showed no significant between-groups difference in mean scores of tinnitus before the intervention (p=.68); whereas, this difference was significant immediately after the intervention (p=.02) and 1h after it (p=.03). The mean score of tinnitus in the anodal stimulation group was significantly lower than the control; whereas, no significant difference was observed between the anodal and cathodal stimulation groups, and between the cathodal and control groups (p >.05). Findings also showed that the mean scores of tinnitus in 2 cathodal stimulation groups (p=.24) and control group (p=.62) were not significantly different at any point; whereas, this score was significantly different in the anodal group at all time points (p=.01).

Jacquemin et al (2018) published the results of a cohort study consisting of both a retrospective and prospective aspect, aiming to compare 2 transcranial direct current stimulation (tDCS) electrode placements and to explore effects of high-definition (HD) tDCS by matched-pairs analyses. The total population (n=78) was split into two groups of 39 participants each. One group (n=39) received tDCS of the dorsolateral prefrontal cortex (DLPFC) and the other (n=39) received tDCS of the right supraorbital-left temporal area (RSO-LTA). Therapeutic effects were assessed with the tinnitus functional index (TFI), a visual analogue scale (VAS) for tinnitus loudness, and the hyperacusis questionnaire (HQ) filled out pretherapy, posttherapy, and follow-up. With a new group of patients and in a similar way, the effects of HD tDCS of the right DLPFC were assessed, with the tinnitus questionnaire (TQ) and the hospital anxiety and depression scale (HADS) added. TFI total scores improved significantly after both tDCS and HD tDCS (DLPFC: \( P <.01 \); RSO-LTA: \( P <.01 \); HD tDCS: \( P =.05 \)). In 32% of the patients, a clinically significant improvement in TFI was observed. The 2 tDCS groups and the HD tDCS group showed no differences on the evolution of outcomes over time (TFI: \( P =.16 \); HQ: \( P =.85 \); VAS: \( P =.20 \)). TDCS and HD tDCS resulted in a clinically significant improvement in TFI in 32% of the patients, with the 3 stimulation positions having similar results.

Direct Current Electrical Stimulation of the Ear

Two randomized trials of transcutaneous electrical stimulation, conducted in the 1980s, reported 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. The dinger 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. Trialists 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 the use of these treatments. A 2015 study, sham-controlled and adequately powered, found no benefit of tDCS. Studies have not shown a benefit for DCS of the ear. The evidence on electromagnetic energy includes a small RCT that found no benefit for the treatment of tinnitus.

**Transmeatal Laser Irradiation**

**Clinical Context and Test Purpose**
The purpose of transmeatal laser irradiation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard therapy, in patients with tinnitus.

The question addressed in this evidence review is: does nonpharmacologic therapies such as transmeatal laser irradiation improve the net health outcome for patients with tinnitus?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest are individuals with tinnitus.

**Interventions**
The therapy being considered is transmeatal laser irradiation.

**Comparators**
Comparators of interest include standard therapy including stress management and noise suppression therapy.

**Outcomes**
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.
**Timing**
The existing literature evaluating transmeatal laser irradiation as a treatment for tinnitus has varying lengths of follow up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

**Setting**
Patients with tinnitus are actively managed by otolaryngologists and primary care providers in an outpatient clinical setting.

**Study Selection Criteria**
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

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 2002 double-blind RCT with 60 patients,\textsuperscript{41} in a 2009 placebo-controlled, double-blind, randomized trial with 60 patients,\textsuperscript{42} a 2014 placebo-controlled, double-blind, randomized trial with 48 patients,\textsuperscript{43} or a 2015 placebo-controlled, double-blind, randomized trial with 66 patients.\textsuperscript{44}

**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**
For individuals who have persistent, bothersome tinnitus who receive psychological coping therapy, the evidence includes RCTs and meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. These therapies are intended to reduce tinnitus impairment and improve health-related quality of life. Meta-analyses of a variety of cognitive and behavioral therapies have found improvements in global tinnitus severity and quality of life, even when tinnitus loudness is not affected. Other RCTs have reported that a self-help/Internet-based approach to cognitive and behavioral therapy or acceptance and commitment therapy may also improve coping skills. The evidence is sufficient to determine that the technology results in a meaningful improvement in health outcomes.
For individuals who have tinnitus who receive sound therapy, the evidence includes RCTs and a systematic review of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on tinnitus masking includes RCTs and a systematic review of RCTs. The RCTs had medium-to-high risk of bias and did not show the efficacy of masking therapy. Research on customized sound therapy appears to be at an early stage. For example, the studies described the use of very different approaches for sound therapy, and it is not yet clear whether therapy is more effective when the training frequency is the same or adjacent to the tinnitus pitch. A 2016 trial, double-blinded and adequately powered, found no benefit of notched music on the primary outcome measures of tinnitus perception and tinnitus distress, although the subcomponent score of tinnitus loudness was reported to be reduced. A benefit on tinnitus loudness but not tinnitus perception or tinnitus distress is of uncertain clinical significance, may be spurious, and would need corroboration in additional studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have tinnitus who receive combined psychological and sound therapy, 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-RCTs. Collectively, the literature does not show consistent improvements in the primary outcome measure (THI scores) when tinnitus retraining therapy is compared with active or sham controls. For Heidelberg neuromusica therapy, a trial has used an investigator-blinded RCT design and showed positive short-term results following treatment. However, the durability of treatment is also unknown. A large, multicenter RCT trial using an intensive, multidisciplinary intervention showed improvement in outcomes. However, it is uncertain whether the multiple intensive interventions used in this trial could be replicated outside of the investigational setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals who have tinnitus who receive electrical or electromagnetic stimulation, the evidence includes a number of sham-controlled randomized trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The available evidence does not currently support the use of these stimulation therapies. A 2015 sham-controlled study that was adequately powered found no benefit of transcranial direct current stimulation.
Moreover, while a 2017 meta-analysis found some benefit for transcranial direct current stimulation, it was noted that further study would be needed to evaluate transcranial direct current stimulation 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 treatment efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

**International Federation of Clinical Neurophysiology**
The International Federation of Clinical Neurophysiology sponsored evidence-based guidelines (2017) on the use of transcranial direct current stimulation (tDCS). The guidelines did not recommend tDCS as a treatment for tinnitus because studies suggested anodal tDCS of the left temporoparietal cortex was probably ineffective (level B evidence). A lack of data precluded any recommendation on the use 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. Table 2 provides some of the Academy’s recommendations.

**Table 4. Guidelines on Treatment of Tinnitus**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>SOR</th>
<th>GOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Clinicians must differentiate patients with bothersome tinnitus from patients with nonbothersome tinnitus”</td>
<td>Strong recommendation</td>
<td>B</td>
</tr>
<tr>
<td>“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”</td>
<td>Recommendation</td>
<td>B</td>
</tr>
<tr>
<td>“Clinicians may recommend sound therapy to patients with persistent, bothersome tinnitus”</td>
<td>Option</td>
<td>C</td>
</tr>
</tbody>
</table>
“Clinicians should recommend cognitive behavioral therapy to patients with persistent, bothersome tinnitus”  Recommendation  A

“Clinicians should not routinely recommend antidepressants, anticonvulsants, anxiolytics, or intratympanic medications for a primary indication of treating persistent, bothersome tinnitus”  Recommendation against  B

“Clinicians should not recommend transcranial magnetic stimulation for the routine treatment of patients with persistent, bothersome tinnitus”  Recommendation against

GOE: grade of evidence; SOR: strength of recommendation.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
The Centers for Medicare & Medicaid Services had a longstanding national coverage determination for tinnitus masking, which was retired in 2014.47

**Ongoing and Unpublished Clinical Trials**
Some ongoing trials that might influence this review are listed in Table 3.

**Table 5. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<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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<tr>
<td>NCT02438891</td>
<td>Evaluation of an Internet-based Sound and Cognitive Behavioral Therapy Course for Treatment for Tinnitus</td>
<td>200</td>
<td>Jul 2018</td>
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<tr>
<td>NCT03026829a</td>
<td>“Cochlear Active Relief From Tinnitus (CART) Sound Therapy” for Tinnitus Relief in Nucleus® Cochlear Implant Users With Tinnitus</td>
<td>50</td>
<td>Feb 2019</td>
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<tr>
<td>NCT Number</td>
<td>Study Title</td>
<td>Phase</td>
<td>Date</td>
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<td>---------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>-------</td>
<td>----------</td>
</tr>
<tr>
<td>NCT02794623</td>
<td>Evaluation of Tinnitus Suppression for Cochlear Implant Recipients</td>
<td>14</td>
<td>Aug 2019</td>
</tr>
<tr>
<td>NCT03022084</td>
<td>Clinical Trial of Sound-Based Versus Behavioral Therapy for Tinnitus</td>
<td>61</td>
<td>Dec 2019</td>
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<tr>
<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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<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></td>
<td><strong>Unpublished</strong></td>
<td></td>
<td></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>
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<td></td>
<td>(completed)</td>
<td></td>
<td></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></td>
<td>(completed)</td>
<td></td>
<td></td>
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<tr>
<td>NCT02293512</td>
<td>A Comparison of CBT and CET Interventions for Veterans With Tinnitus</td>
<td>40</td>
<td>Nov 2016</td>
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<tr>
<td></td>
<td>(completed)</td>
<td></td>
<td></td>
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<tr>
<td>NCT01177137</td>
<td>Tinnitus Retraining Therapy Trial</td>
<td>151</td>
<td>Feb 2017</td>
</tr>
<tr>
<td></td>
<td>(completed)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03068871</td>
<td>A Comparison of Two Psycho-educational Group Interventions for Tinnitus Patients</td>
<td>45</td>
<td>July 2017</td>
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<tr>
<td></td>
<td>(completed)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02653547</td>
<td>Influence of Treatment Duration and Stimulation Frequency on Repetitive Transcranial Magnetic Stimulation in Chronic Tinnitus</td>
<td>80</td>
<td>May 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* 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)

**S8948** Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes
<table>
<thead>
<tr>
<th>Date</th>
<th>Update Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/1/08</td>
<td>New policy; considered investigational.</td>
</tr>
<tr>
<td>9/1/09</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>9/1/10</td>
<td>Policy statement revised to list tinnitus coping therapy, transcutaneous electrical stimulation, and sound therapy as investigational.</td>
</tr>
<tr>
<td>9/1/11</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>9/1/12</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>9/1/13</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>9/1/14</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>9/1/15</td>
<td>No policy statement changes. Added additional coding info for CPT 97026 and S8948.</td>
</tr>
<tr>
<td>9/1/16</td>
<td>Policy statement reordered and “surgical” added to the note on topics that the policy does not address.</td>
</tr>
<tr>
<td>4/1/17</td>
<td>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)</td>
</tr>
<tr>
<td>9/1/17</td>
<td>No policy statement changes.</td>
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<tr>
<td>4/1/18</td>
<td>The medically necessary statement revised to define psychological coping therapy; biofeedback added to the investigational statement.</td>
</tr>
<tr>
<td>9/1/18</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>9/1/19</td>
<td>No policy statement changes.</td>
</tr>
</tbody>
</table>

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.