Policy Number	**MED205.022**
Policy Effective Date	**08/01/2026**

Treatment of Tinnitus

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Coverage

Psychological coping therapy including cognitive-behavior therapy (CBT), self-help CBT, tinnitus coping therapy, acceptance and commitment therapy, and psychophysiological treatment (which may include biofeedback), **may be considered medically necessary** for persistent (duration ≥6 months) and bothersome tinnitus.

Treatment of tinnitus with any of the following therapies **is considered experimental, investigational and/or unproven:**

- Tinnitus maskers, customized sound therapy;
- Biofeedback (not done in conjunction with psychophysiological treatment);
- 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 treatment of tinnitus (e.g., cochlear or brainstem implants), pharmacologic treatment of tinnitus (e.g., use of amitriptyline or other tricyclic antidepressants), or injection of botulinum toxin (see medical policy RX501.019).

Policy Guidelines

Psychological therapies typically require 4 to 6 one-hour visits over an 18-month period.

Description

Various non-pharmacologic 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.

Background

Tinnitus

Tinnitus describes the perception of any sound in the ear in the absence of an external stimulus and presents as a malfunction in the processing of auditory signals. A hearing impairment, often noise-induced or related to aging, is commonly associated with tinnitus. Clinically, tinnitus is subdivided into subjective and objective 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 lead 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 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 the extinction of the subconsciously 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) 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 the 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 U.S. Food and Drug Administration

Devices	Manufacturer	Date Cleared	501(k) No.	Indication
Peace N Quiet	PNQ Health	02/27/2024	K233435	Tinnitus Relief
Tinearity G1 (6103); Tinearity G1 Adapters X3 (6042)	Duearity AB	06/30/2023	K223694	Tinnitus Relief
Tinnitogram Signal Generator	Goldenear Company, Inc.	02/01/2023	K221168	Tinnitus Relief

Silentcloud	Aureliym GmBH	01/04/2023	K221125	Tinnitus Relief
Multiflex Tinnitus Technology	Starkey Laboratories	06/19/2020	K201370	Tinnitus Relief
Tinnitus Sound Generator Module	GN Hearing A/S	02/20/2020	K193303	Tinnitus Relief
Tinnitus Sound Generator Module	GN Hearing A/S	11/30/2018	K180495	Tinnitus Relief
Audifon Tinnitus-Module	Audiofon USA Inc.	10/19/2017	K171243	Tinnitus Relief
Tinnilogic Mobile Tinnitus Management De	Jiangsu Betterlife Medical Co., Ltd.	5/17/2017	K163094	Tinnitus Relief
Sound Options Tinnitus Treatment	Sound Options Tinnitus Treatments Inc.	9/28/2016	K161562	Tinnitus Relief
Hypersound Tinnitus Module	Turtle Beach Corporation	8/23/2016	K161331	Tinnitus Relief
Desyncra For Tinnitus Therapy System, De	Neurotherapies Reset Gmbh	1/20/2016	K151558	Tinnitus Relief
Reve134	Kw Ear Lab, Inc.	10/9/2015	K151719	Tinnitus Relief
Serenity	Sanuthera, Inc.	7/27/2015	K150014	Tinnitus Relief
Soundcure Serenade Tinnitus Treatment Sy	Soundcure, Inc.	4/13/2015	K150065	Tinnitus Relief
Levo Tinnitus Masking Software Device	Otoharmonics Corp.	7/18/2014	K140845	Tinnitus Relief
Solace Sound Generators	Amplisound Hearing Products & Services	3/25/2014	K132965	Tinnitus Relief
Tinnitus Sound support	Oticon A/S	3/18/2014	K133308	Tinnitus Relief
Wave 2g, Soul	Hansaton Akustik Gmbh	1/3/2014	K130937	Tinnitus Relief

Rationale

Medical policies 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. Randomized controlled trials 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 the assessment and treatment of tinnitus, which is now archived. (1) Treatments evaluated included laser, repetitive transcranial magnetic stimulation (rTMS), 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, and low-level evidence for no effect of CBT on subjective loudness, sleep disturbance, anxiety, depression, and global quality of life. Evidence was insufficient for other psychological and behavioral interventions such as tinnitus retraining therapy and relaxation.

Psychological Coping Therapy for the Treatment of Tinnitus

Clinical Context and Therapy Purpose

Many treatments are supportive because, currently, there is no cure. Psychological therapies may be provided to improve coping skills, typically requiring 4 to 6 one-hour visits over an 18-month period, in individuals with persistent, bothersome tinnitus. Self-help and internet-based therapies may also be used.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with persistent, bothersome tinnitus.

Interventions

The therapy being considered is psychological coping therapies, which may include cognitive, behavioral, acceptance and commitment therapy, mindfulness, and cognitive and behavioral (combined) interventions.

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. Commonly used self-report questionnaires include the Tinnitus Handicap Inventory (THI), Tinnitus Questionnaire (TQ), Tinnitus Functional Index (TFI), and Tinnitus Handicap Questionnaire (THQ). (2, 3)

- The THI is scored from 0 to 100, with a difference of 7 points estimated as the minimal clinically important difference. (4)
- The TQ has 52 items that assess emotional and cognitive distress, intrusiveness, hearing difficulties, sleep disturbance, and somatic complaints.
- The THQ has 27 items covering social, emotional, and behavioral effects; hearing difficulties; and outlook on tinnitus.
- The TFI is a 25-item questionnaire scoring the severity and negative impact of tinnitus in the domains of intrusiveness, sense of control, cognitive complaints, sleep disturbance, auditory difficulties, relaxation, quality of life and emotional distress. The TFI is designed to be more sensitive to change, for which the patient must answer each item on a Likert scale from 0 to 10, with higher numbers indicating greater distress. The minimal clinically important difference of the TFI is considered to be 13 points. (3)

Consensus recommendations on core outcome measures in tinnitus suggest that different domains would be appropriate for different interventions. (3) For sound therapy, the most relevant domains would be intrusiveness, ability to ignore, concentration, quality of sleep, and sense of control. The committee concluded that for psychological therapies, domains of intrusiveness, acceptance, mood, negative thoughts and beliefs, and sense of control were considered more appropriate.

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 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 1 year of follow-up is considered necessary to demonstrate efficacy.

<u>Study Selection Criteria</u>
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.

Systematic Reviews

Characteristics and results of recent meta-analyses are shown in Tables 2, 3, and 4.

An updated Cochrane review by Fuller et al. (2020) evaluated cognitive, behavioral, acceptance and commitment therapy, mindfulness, and cognitive and behavioral (combined) interventions for tinnitus. (4) The authors included 28 studies with 2,733 participants on in-person or internet-provided CBT for the treatment of tinnitus. There was evidence that CBT led to a clinically significant improvement in quality of life at 3 to 22 weeks compared to no intervention or tinnitus retraining therapy, and evidence that CBT may improve quality of life compared to audiological care or other active controls (e.g., relaxation, information, internet-based discussion forums). Subgroup analyses examining the mode of delivery (bibliotherapy, face-to-face and internet-based) indicated no significant differences between the modes of delivery. The certainty of conclusions for the primary outcome and secondary outcomes (depression, anxiety, health-related quality of life, and negative interpretation of tinnitus) were generally considered low or very low. Adverse effects of the treatment were rare.

Table 2. Meta-Analyses Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Fuller et al. (2020) (4)	2009-2018	28	Patients with tinnitus for at least 3 months	2,733	RCT	3 to 22 weeks
Landry et al. (2019) (5)	1985-2017	19	Adult patients with tinnitus	1,543 (23 to 304)	RCT	1 to 15 weeks

RCT: randomized controlled trial.

Table 3. Cochrane Meta-Analysis Results

Study	Quality of Life	Depression	Anxiety	HR-QOL	Negative Interpretation
Fuller et al. (2020) (4)					
CBT vs. No Intervention/Wait list Control					
Studies	10	8	6	2	
N	537	502	429	170	
SMD (95% CI)	-0.56 (-0.83 to -0.30)	-0.34 (-0.60 to -0.08)	-0.45 (-0.82 to -0.09)	-0.38 (-0.67 to -0.08)	No difference
THI Difference	-10.91				
Level of Certainty	Low	Low	Very low	Very low	Very low
CBT vs. Audiological Care					

Studies	3				
N	444				
THI Difference (95% CI)	-5.65 (-9.79 to -1.50)	May reduce	No difference	No difference	–4.68 (-6.94 to –2.43)
Level of Certainty	Moderate	Low	Low	Low	Low
CBT vs. Tinnitus Retraining Therapy					
Studies	1				1
N	42				42
THI Difference	-15.79 (-27.91 to -3.67)	Uncertain	Uncertain	Uncertain	-9.78 (-16.40 to -3.16)
Level of Certainty	Low	Low	Low	Low	Low
CBT vs. Other Active Control					
Studies	12	11	11	1	5
N	966	943	943	95	455
SMD	-0.30 (-0.55 to -0.05)	-0.17 (-0.33 to -0.01)	-0.17 (-0.33 to -0.01)	Uncertain	-0.55 (-0.75 to -0.35)
Level of Certainty	Low	Low	Low	Very low	Moderate

CBT: cognitive behavioral therapy: CI: confidence interval; HR-QOL: health-related quality of life; SMD: standardized mean difference; THI: Tinnitus Handicap Inventory.
Minimal clinically important difference on the tinnitus handicap questionnaire=7 points on a 0-to-100-point scale.

Landry et al. (2019) performed a network meta-analysis of the effect of various forms of cognitive and/or behavioral therapy on tinnitus-related quality of life, depression, and anxiety (Table 4). (5) Tinnitus loudness was not assessed, as an earlier Cochrane review had concluded that CBT altered the impact of tinnitus, but not tinnitus loudness. Twelve studies were included in a pairwise meta-analysis of active therapy versus waitlist controls and 19 studies were included in the network meta-analysis that compared various forms of CBT. All the studies were rated as at high-risk of bias characterized by lack of blinding, high drop-out rates, and lack of intent-to-treat analysis. Heterogeneity was high, driven largely by the positive results of 2 studies that assessed internet-based CBT. Both self-administered and face-to-face CBT were found to be superior to a waitlist control for health-related quality of life and tinnitus-related depression. Ranking suggested that guided self-administered CBT was the most effective treatment in improving tinnitus-specific health-related quality of life, depression, and anxiety, although there was no statistical difference between the treatments. It was noted that the greater effect size of self-administered CBT protocols may be related to motivation levels in patients who volunteer for self-administered therapy.

Table 4. Network Meta-Analysis Results

Study (Year)	HR-QOL	Depression	Anxiety
Landry et al. (2019) (5)			
Total N	1,111	925	309

Active Therapy vs. Waitlist Control			
SMD (95% CI)	1.46 (0.67 to 2.24)	0.95 (0.2 to 1.7)	1.85 (-0.06 to 3.75)
I^2 (p)	95.3%	93.7%	97%
Group CBT (Face to Face)			
SMD (95% CI)	0.75 (0.53 to 0.97)	0.39 (0.17 to 0.60)	0.52 (0.03 to 1.01)
I^2 (p)	0.0% (0.767)	0.0% (0.558)	0.0% (0.719)
Mixed CBT (Self-administered)			
N			
SMD (95% CI)	3.44 (0.22 to 7.09)	2.80 (1.64 to 7.23)	4.17 (3.65 to 4.60)
I^2 (p)	99.0% (0.00)	99.0% (0.00)	2.5% (0.311)

CI: confidence interval; CBT: cognitive-behavioral therapy; HR-QOL: health-related quality of life; SMD: standardized mean difference.

Randomized Controlled Trials

Walter et al. (2025) conducted an RCT of app-based CBT in 187 patients with tinnitus. (6) Patients in the app-based CBT group started therapy at the time of randomization; the other group started with 3 months of waiting, then started the app-based CBT therapy. Efficacy was evaluated after 3 and 9 months of treatment compared to baseline, with change in TQ scores as the primary outcome. At 3 months, mean (standard deviation [SD]) TQ scores were 23.4 (11.8) in the group that started therapy at the time of randomization compared to 24.8 (15.7) in patients who waited to start therapy (p<.001). At 9 months, mean (SD) TQ scores were 17.6 (10.2) and 20.3 (13.0), respectively (p<.001). Comparative findings for changes in quality of life scales were not presented for individuals who started therapy at the time of randomization versus those who started therapy later.

Theodoroff et al. (2021) compared the relative efficacy of CBT and acoustic coordinated reset neuromodulation therapy using the Desyncra™ tinnitus device in 61 patients with primary and persistent tonal tinnitus. (7) These patients were randomly assigned to CBT (n=32) or Desyncra (n=29) with stratification according to current hearing aid use. The number of study visits varied according to group assignment and ranged from approximately 7 to 12 visits. The main outcome measure was the TQ. Across all treatment arms and strata mean TQ scores decreased post-baseline from 5 to 15 points. In the no hearing aid stratum, there was a difference of -2.0 TQ points favoring Desyncra at 24 weeks and, in the hearing aid stratum, a difference of -1.0 points favoring Desyncra. Overall, the results suggest that Desyncra is just as effective or more so than CBT in reducing tinnitus distress; however, there is considerable uncertainty in this outcome as the focus of this study was on relative efficacy.

Xing et al. (2021) evaluated the impact of cognitive training on 64 adults with subjective idiopathic non-pulsatile tinnitus causing significant tinnitus-related distress in an online, prospective, open-label, RCT. (8) Enrolled patients (N=125) were randomly assigned to auditory-intensive exercises using the Brain HQ Auditory Intensive regimen (n=62) or an active control utilizing non-auditory intensive games (n=63). Both groups performed training for 20 minutes per day, 5 days per week, for 8 weeks with surveys completed at baseline, 8 weeks, and 12 weeks. The primary outcome measure was the change in TFI scores with secondary

outcome measures including scores on the Tinnitus Global Bothersome Scale, Cognitive Failures Questionnaire, Beck Anxiety Inventory, and the Patient Health Questionnaire-9. Results revealed that the within-subject change in TFI was not different between the intervention and control groups, with marginal mean differences of 0.24 (95% confidence interval [CI], -11.20 to 10.7) and 2.17 (95% CI, -8.50 to 12.83) at 8 weeks and 2.33 (95% CI, -8.6 to 13.3) and 3.36 (95% CI, -7.91 to 14.6) at 12 weeks, respectively. When comparing the 2 groups directly, the control group had non significantly higher TFI scores than the intervention group at baseline, 8 weeks, and 12 weeks. No major differences in any of the secondary outcomes were observed. The study was limited by its open-label design and the fact that data gathered through the various outcome measures were subjective and susceptible to recall bias.

Section Summary: Psychological Coping Therapies

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 quality of life. Meta-analyses of a variety of CBTs reported improvements in global tinnitus severity and quality of life, even when tinnitus loudness was not affected. There is evidence that self-help and internet-based therapies may be as effective as traditional group therapy for various forms of behavioral and cognitive therapies. Overall, the literature indicates that psychological therapies can improve coping skills and quality of life and may decrease tinnitus-associated distress and annoyance.

Sound Therapy for Treatment of Tinnitus

Clinical Context and Therapy Purpose

One treatment, called tinnitus masking therapy, has focused on the use of devices worn in the ear that produce a broad band of continuous external noise that drowns out or masks the tinnitus. 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 individuals' 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 subconsciously 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 another 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)

prerecorded with selected relaxation audio and other sounds spectrally adapted to the individual's hearing thresholds. This is achieved by boosting the amplitude of those frequencies at which an audiogram has shown the individual 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 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 the notched music is that tinnitus is triggered by injury to the 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 the reorganization of the brain.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is 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. Commonly used self-report questionnaires include the THI, TQ, TFI, and the THQ as described above.

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

<u>Study Selection Criteria</u>
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.

Tinnitus Masking

A 2018 Cochrane review evaluated the evidence for masking in the management of tinnitus in adults. (9) Eight RCTs (N=590 participants) were included that used noise-generating devices and/or hearing aids as the sole management tool or in combination with other strategies, including counseling. Seven studies looked at hearing aids, 3 evaluated sound generators, and 4 evaluated combination devices. The quality of the evidence was low. Risk of bias was unclear and there was little blinding. No studies were identified that compared masking devices with a wait-list control or other control group. Reviewers concluded that it was uncertain whether a masking device (hearing aid, sound generator, or combination) would result in any difference in tinnitus symptom severity.

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. (10)

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. (11) 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 to 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 two 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 to 6.8 hours/day). The two 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 Tinnitus Reaction Questionnaire (TRQ) scores improved for the combined customized acoustic stimuli group over the 12 months of the study. These 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 same acoustic device described results for the first 552 patients who received treatment at specialized clinics in Australia. (12) 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 decibel (dB) hearing loss). 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%) 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 versus desensitization.

Auditory Discrimination Training

Herraiz et al. (2010) randomized 45 patients who scored mild or moderate (<56) on the THI to auditory discrimination training with the same frequency as the tinnitus pitch or training on a frequency near to, but not the same as, the tinnitus pitch. (13) 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 VAS 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

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. (14) 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 hours/week), 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-blind and adequately powered RCT of notched music training in 100 participants with tonal tinnitus. (15) 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 intention-to-treat or per-protocol analysis, although the subscale of tinnitus loudness was reported to be reduced.

Atipas et al. (2021) completed a double-blind RCT that compared tailor-made notched music therapy to ordinary music in 104 adults in Thailand with chronic subjective tinnitus for more than 3 months. (16) Tinnitus matching was performed on all patients before 1:1 random allocation. The severity of tinnitus symptoms and treatment outcomes were assessed using the THI questionnaire and a VAS. Patients were evaluated at 1, 3, and 6 months. At baseline, there were no significant differences between the groups except for gender; the female-to-male ratio for the treatment group was 0.79 compared with 1.74 for the control (p=.049). Results revealed no significant differences in any variable between the treatment and control groups; however, an overall greater nonsignificant reduction in THI and VAS scores were noted in the tailor-made notched music therapy versus ordinary music group during the follow-up period. Interpretation of this study was limited due to failure of patients to attend some or all of the follow-up sessions.

Piromchai et al. (2021) compared notched music therapy, conventional music therapy, and counseling in a 3-arm, single-blind, RCT conducted at a single center in Thailand. (17) Adults with a THI score of at least 38 and General Health Questionnaire-28 score of <6 was randomly assigned to notched music therapy (n=25), conventional music therapy (n=24), or counseling (n=26) with follow-up at months 1, 2, and 3 after therapy initiation. The study outcomes included THI score, Pittsburgh Sleep Quality Index (PSQI) score, and adverse events. At baseline, demographic data were similar among the groups. Results revealed that the mean differences in THI score from baseline in the notched music therapy, conventional music therapy, and counseling groups at 3 months were 20.5 (95% CI, 10.2 to 30.8), 27.8 (95% CI, 17.7 to 38), and 17.79 (95% CI, 6.8 to 28.8) points, respectively (p=.008, <.001, and <.001 respectively). Among the groups, there was no significant difference in terms of THI score at any time point (p >.05). Additionally, there was no significant difference among groups in PSQI score at any time point (p >.05) and no complications were reported among the groups. Overall, in this first RCT to

compare notched music therapy, conventional music therapy, and counseling, all treatments significantly reduced tinnitus severity with no differences among the treatments observed.

Tong et al. (2023) reported the results of a single-blind RCT of tailor-made notched music therapy (n=60) to tinnitus retraining therapy (n=60) in adults with subjective tinnitus for ≥6 months at a single center in China. (18) Both interventions were delivered through a mobile phone platform. Eight participants dropped out prior to study commencement and were excluded from the analysis, and another 15 participants did not attend all follow-up visits. At study enrollment, participants had a mean age of 42.8 years with mean THI and VAS scores of 41 and 4.4, respectively. In the notched music therapy group, baseline THI was 41.5 (standard deviation [SD], 21.74), which decreased to 24.7 (SD, 17.33) at 1-month post-treatment and further to 21.72 (SD, 18.21) at 3 months post-treatment; both 1- and 3-month THI scores differed significantly from the baseline value (p<.001). In the tinnitus retraining therapy group, the finding was similar, with scores significantly decreasing from baseline levels (40.56; SD, 19.45) through 1 (31.59; SD, 18.07) and 3 months (27.89; SD, 18.48) follow-up. The between-group difference in THI was -6.90 points (95% Cl, -13.53 to -0.27) at 1 month follow-up favoring the notched music therapy group, but no significant difference was observed at 3 months post-treatment (-6.17; 95% Cl, -13.04 to 0.71). VAS scores in the notched music therapy and tinnitus retraining therapy groups showed a significant decrease (p<.001) from baseline values (4.29; SD, 1.94 and 4.59; SD, 1.68) compared to 1 month (3.52; SD, 1.6 and 3.74; SD, 1.75) and at 3-month (3.17; SD, 1. 72 and 4; SD, 2.06) VAS scores. No significant difference was noted in VAS scores between groups at 1-month post-treatment, but at 3 months, the notched music therapy group had a significantly lower score (p<.001). Interpretation of this study was limited due to the failure of patients to attend some or all of the follow-up sessions, non-standardization of the tinnitus retraining therapy comparator, a lack of power calculations, lack of an intention to treat analysis, and being conducted at a single non-U.S. center.

Tavanai et al. (2024) conducted a systematic review and meta-analysis of 5 RCTs that evaluated tailor-made notched music training for tinnitus. (19) Among the 5 RCTs, there was no significant effect on THI scores at 3 (effect size, -0.99; 95% CI, -2.94 to 0.96; I^2=95.0%) and 6 months (effect size, -1.81; 95% CI, -5.64 to 2.01; I^2=97.5%). Although 4 studies assessed the outcome of VAS scores, there was not enough data to perform a meta-analysis.

Sound Options Tinnitus Treatments

Li et al. (2016) reported on a double-blind 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 (e.g., tonal, ringing, hissing, primary frequency). (20) 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, 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 scores 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 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 the 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-blind 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. Two more recent RCTs evaluating notched music therapy for tinnitus found no significant differences in efficacy between this approach and ordinary music therapy or counseling. One additional RCT found tailor-made notched music therapy and tinnitus retraining therapy both improved THI and VAS scores from baseline to 3 months follow-up, but the notched music therapy group had significantly improved THI scores at 1-month follow-up and VAS scores at 3 months follow-up compared to tinnitus retraining therapy. 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 Therapy 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 individuals with tinnitus.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is 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. Commonly used self-report questionnaires include the THI, TQ, TFI, and the THQ as described above.

The existing literature evaluating combined psychological and sound therapy as a treatment for tinnitus have varying lengths of follow-up. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, a year of follow-up is considered necessary to demonstrate efficacy.

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.

Tinnitus Retraining Therapy
Alashram (2024) reported the results of a systematic review of 15 RCTs (N=2069) that used tinnitus retraining therapy in patients with tinnitus. (21) The review found that tinnitus retraining therapy was not superior to usual care or other tinnitus therapies (i.e., tinnitus masking, educational counseling, tinnitus retraining with open ear hearing aids, or tailored notched music training).

Goshtasbi et al. (2025) conducted an RCT of cognitive behavioral therapy plus customized sound therapy delivered via smartphone. (22) The 92 patients received daily sound therapy and weekly interactive cognitive behavioral therapy or wait-list control for 8 weeks. Patients who received the intervention had greater improvements in TFI, Patient Health Questionnaire-9, Generalized Anxiety Disorder-7, and Pittsburgh Sleep Quality Index scores (all $p<.01$) compared to patients in the control group.

Ji et al. (2024) conducted an RCT of cognitive behavioral therapy plus refined sound therapy in 100 patients with tinnitus. (23) The control group received post-auricular injections of lidocaine and methylprednisolone sodium succinate. There was a significantly greater reduction in THI, Self-Rating Depression Scale, Hamilton Anxiety Rating Scale, and VAS scores in the cognitive behavioral therapy plus refined sound therapy group compared to the control group (all $p<.05$).

An RCT by Westin et al. (2011) compared results of tinnitus retraining with acceptance and commitment therapy (ACT), or waiting-list control in 64 patients with normal hearing. (24) 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 scores 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). (25) 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. (26) Following initial screening for tinnitus severity and motivation to comply with the 18-month study, 59 subjects were enrolled in the tinnitus masking condition (mean age, 61 years), and 64 were enrolled in tinnitus retraining (mean age, 59 years). Treatment included appointments with tinnitus specialists at 3, 6, 12, and 18 months to check the ear-level devices and to receive the group-specific counseling (about 4 to 5 hours total). At each visit, the subjects completed the THI, THQ, 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 effect sizes (range, 0.57 to 0.66) were reported for the tinnitus retraining group and, after 18 months of treatment, major effect sizes (range, 0.77 to 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 (27) and a systematic review by Grewal et al. (2014). (28)

Beyond the RCTs noted above, Scherer et al. (2019) compared the effect of tinnitus retraining therapy (full and partial) versus standard of care on tinnitus-related quality of life in the randomized, placebo-controlled, multicenter, Tinnitus Retraining Therapy Trial (TRTT). (29) Table 5 summarizes the key characteristics of the TRTT study. The 3 interventions not only allowed the investigators to compare tinnitus retraining therapy to standard of care counseling,

but also evaluate the contributions of sound therapy and tinnitus-specific educational counseling. The primary outcome of the TRTT study was the mean change in TQ score from baseline to follow-up, assessed at 3, 6, 12, and 18 months. There were a variety of secondary outcomes including scores on the TFI and THI. The mean patient age was 50.6 years, 29% were women, and 23.8% reported belonging to a minority group including 11.3% of Hispanic or Latino origin. Key results of the study are summarized in Table 6. Overall, longitudinal analyses revealed no difference between partial or full tinnitus retraining therapy compared with standard of care, or partial versus full tinnitus retraining therapy on TQ, TFI, or THI total scores. About 50% of all patients in the TRTT study showed clinically meaningful reductions in the effect of tinnitus on their daily lives. The TRTT study was limited by a larger than expected number of missed visits and withdrawals (mainly in the full and partial tinnitus retraining therapy groups) and lack of study clinician expertise in providing tinnitus retraining therapy at the time of study onset.

Table 5. Summary of Key RCT Characteristics

Study; Trial	**Countries**	**Sites**	**Dates**	**Participants**	**Interventions**	
					Active	**Comparator**
Scherer et al. (2019) (29)	U.S.	6 military hospitals	2011-2017	N=151 active-duty and retired military personnel and their dependents; eligible participants had subjective distressing tinnitus for at least 1year with no evidence of a medical cause, functionally adequate hearing sensitivity, no treatment for tinnitus within the past year, and a score of 40 or more on the TQ	Full tinnitus retraining therapy, including tinnitus-specific educational counseling and low-level broadband sound therapy implemented with ear-level sound generators (n=51) Partial tinnitus retraining therapy, including tinnitus-specific educational	Standard of care involving a patient-centered counseling protocol (n=49)

					counseling and placebo ear-level sound generators (n=51)	

RCT: randomized controlled trial; TQ: Tinnitus Questionnaire; U.S.: United States.

Table 6. Summary of Key RCT Results

Study	TQ (Mean [SD] difference from baseline to 18 months)	TFI (Mean [SD] difference from baseline to 18 months)	THI (Mean [SD] difference from baseline to 18 months)	10-Point VAS (Mean [SD] difference from baseline to 18 months)
Scherer et al. (2019) (29)				
Tinnitus retraining therapy (n=34)	-18.2 (15.1)	-6.7 (18.5)	-6.1 (18)	-1.8 (3.0)
Partial tinnitus retraining therapy (n=40)	-19 (15.9)	-14.4 (17.2)	-12.6 (17.1)	-2.1 (2.4)
Standard of care (n=37)	-16.5 (16.3)	-10.3 (21.9)	-9.4 (17.7)	-1.8 (2.8)
Effect size (95% CI)	Tinnitus retraining therapy: -1.32 (-1.78 to -0.85) Partial tinnitus retraining therapy: -1.16 (-1.56 to -0.76) Standard of care: -1.01 (-1.41 to -0.61)	Tinnitus retraining therapy: -0.37 (-0.71 to -0.02) Partial tinnitus retraining therapy: -0.85 (-1.21 to -0.48) Standard of care: -0.47 (-0.81 to -0.13)	Tinnitus retraining therapy: -0.34 (-0.69 to 0.02) Partial tinnitus retraining therapy: -0.74 (-1.09 to -0.38) Standard of care: -0.53 (-0.87 to -0.18)	Tinnitus retraining therapy: -0.58 (-0.97 to -0.18) Partial tinnitus retraining therapy: -0.85 (-1.26 to -0.43) Standard of care: -0.64 (-1.01 to -0.26)

CI: confidence interval; RCT: randomized controlled trial; SD: standard deviation; TFI: Tinnitus Functional Index; THI: Tinnitus Handicap Inventory; TQ: Tinnitus Questionnaire; VAS: visual analog scale.

Heidelberg Neuro-Music Therapy

Argstatter et al. (2015) reported on a 2-center, investigator-blinded RCT with 290 patients treated with neuro-music therapy or a single counseling session. (30) Therapy was provided in 8 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

Goshtasbi et al. (2025) conducted an RCT that compared app-based customized sound therapy plus CBT to standard therapy (wait list) in 92 patients with tinnitus. (22) After 8 weeks, the mean (SD) change in TFI score from baseline (the primary endpoint) was 16.7 (14.9) versus 1.9 (10.8) in the treatment and control groups, respectively (p<.001). Differences in several quality of life measures were also significantly greater in the treatment group versus the control group. The clinical relevance of these findings may be limited due to the large standard deviation in TFI scores in the treatment group, which suggests that not all patients achieved a minimal clinically important difference.

Schiosswohl et al. (2025) reported on an international RCT of multiple combinations of tinnitus therapy (n=231) compared to monotherapy (n=230) in adult patients who had tinnitus for ≥6 months. (31) Pharmacotherapy for tinnitus was allowed at stable doses. and no treatments could have been started within the 3 months before randomization. Sound therapy (via an app) was studied alone and in combination with CBT, app-based structured counseling, and hearing aids, for a total of 10 treatment arms. The study period consisted of 12 weeks. The primary outcome was the difference in baseline versus 12-week THI between monotherapy and combination therapy groups. At week 12, the change in THI scores among all patients receiving monotherapy was -11.7 (95% CI, -14.4 to -9.0) and -14.9 (95% CI, -17.7 to -12.1) in the combination therapy groups (p=.034). For sound therapy alone (n=59), the change from baseline in THI was -3.8 (95% CI, -9.3 to 1.6), which is less than the minimally clinically important difference for the THI scale. Sound therapy in combination with CBT (n=51), structured counseling (n=63), and hearing aids (n=27) had changes in THI at 12 weeks of -14.1 (95% CI, -19.8 to -8.4), -12.7 (95% CI, -17.8 to -7.5), and -12.9 (95% CI, -20.5 to -5.3), respectively. The corresponding Cohen's d statistics were 0.24 (small effect), 0.8 (large effect), 0.71 (moderate effect), and 0.78 (moderate effect).

Cima et al. (2012) reported on a large RCT of usual care versus a combination of approaches. (32) Of the 741 untreated patients who were screened, 247 were assigned to usual care (e.g., hearing aids and up to 9 sessions with a social worker) and 245 were assigned to a specialized care protocol. Specialized care included 105 minutes of audiologic diagnostics, 30 minutes of audiologic rehabilitation (hearing aid or masking device), 120 minutes of CBT education, 60 minutes of intake psychology, 40 minutes of audiologic follow-up, and 24 hours of group behavioral and cognitive therapies. About a third of the patients in each group were lost to follow-up at 12 months. Compared with usual care, at 12 months, specialized care resulted in a

modest improvement in health-related quality of life (effect size, 0.24), decrease in tinnitus severity (effect size, 0.43), and decrease in tinnitus impairment (effect size, 0.45).

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 or TQ score) when tinnitus retraining therapy is compared with active or sham controls. For Heidelberg neuro-music 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. Another RCT found that sound therapy combined with other interventions (e.g., CBT, structured counseling) was more effective than sound therapy alone, but the number of patients in each arm was small and larger trials are needed to confirm these findings.

Repetitive Transcranial Magnetic Stimulation (rTMS) for Treatment of Tinnitus

Clinical Context and Therapy Purpose

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

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with tinnitus.

Interventions

The therapy being considered is rTMS.

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. Commonly used self-report questionnaires include the THI, TQ, TFI, and the THQ as described above.

The existing literature evaluating rTMS 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 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 6 months of follow-up is considered necessary to demonstrate efficacy.

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.

Systematic Reviews

He et al. (2025) conducted a meta-analysis of 16 RCTs (N=1105) that evaluated rTMS for chronic tinnitus. (33) Eleven trials were included in the meta-analysis, which found that rTMS had a significant effect on THI scores compared to sham rTMS (mean difference, -11.54; 95% CI, -17.32 to -5.77; I^2=84%; p<.0001). There was a greater effect of rTMS in the short term (at 1 month) compared to longer term (6 months). In a meta-analysis of 4 studies, there was a significant difference in VAS scores with rTMS (mean difference, -1.85; 95% CI, -2.26 to -1.45; I^2=0%; p<.0001) but there was no effect of rTMS on TQ scores (mean difference, -2.96; 95% CI, -6.69 to 1.57; I^2=47%; p=.22).

Soleimani et al. (2016) published a systematic review of 15 double-blind, randomized trials with sham controls on rTMS. (34) 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 to 20 patients). A qualitative review of the 15 trials found significant benefit of rTMS in 9 trials and no significant effect in 6 trials. There was significant heterogeneity in the population, target brain area, stimulation parameters, and length of follow-up.

Randomized Controlled Trials

The largest study included in the 2016 systematic review is that of Langguth et al. (2014). (35) 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. (36) 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 Therapy Purpose

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. Invasive electrical stimulation of various cortical areas or nerves has also been evaluated.

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

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is 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. Commonly used self-report questionnaires include the THI, TQ, TFI, and the THQ as described above.

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 1 outcome of interest, longer follow-up is necessary to fully observe outcomes.

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.

Transcranial Direct Current Stimulation
Song et al. (2012) published a systematic review of transcranial direct current stimulation (tDCS) for the treatment of tinnitus. (37) 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%. A meta-analysis of 2 RCTs showed a medium-to-large effect size 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. (38) The authors 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. (39) 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 Abtahi et al. (2018), was conducted in Al-Zahra Hospital in Isfahan between 2015 and 2016. (40) In this trial, 51 patients who had tinnitus for at least 1 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 1 of 3, equal-size arms: anodal stimulation group, cathodal stimulation group, and control group. The subjects received 20-minute 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 1 hour after (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 the 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).

Cardon et al. (2022) conducted an RCT of tDCS at 2 sites (left temporal area and right dorsolateral prefrontal cortex) in 77 patients with tinnitus. (41) Sham tDCS was used in the control group. A total of 6 sessions were given. At 8 weeks after the end of treatment, there was no difference in the TFI scores between tDCS and sham treatment (p=.86). A greater change in TFI scores was seen in males and in individuals with higher anxiety symptom scores at baseline. The small sample size could have led to a lack of power to detect a difference between groups.

Jacquemin et al. (2018) published the results of a cohort study consisting of both a retrospective and prospective aspect, aiming to compare 2 tDCS electrode placements and to explore effects of high-definition (HD) tDCS by matched-pairs analyses. (42) The total population (n=78) was split into 2 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. Therapeutic effects were assessed with the TFI, a VAS for tinnitus loudness and the hyperacusis questionnaire 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 TQ and the hospital anxiety and depression scale added. TFI total scores improved significantly after both tDCS and HD tDCS (DLPFC: p<.01; right supraorbital-left temporal area: 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 in the evolution of outcomes over time (TFI: p=.16; hyperacusis questionnaire: 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.

Transcutaneous Electrical Nerve Stimulation

Byun et al. (2020) reported a systematic review of 17 studies (1215 patients) on transcutaneous electrical nerve stimulation (TENS) of a variety of sites. (43) Most stimulation sites were on the auricle, but some studies placed electrodes on the finger and back. There were 4 level 2 RCTs, a single level 3 study, and the rest were case series. Three studies were combined for meta-analysis of pre-treatment to post-treatment THI and VAS loudness. Meta-analysis showed a decrease in THI (-7.55; 95% CI, -10.93 to -4.18, p<.001) and a modest decrease in VAS (-0.65; 95% CI, -0.99 to -0.30, p<.001). Subjective suppression of tinnitus in these unblinded studies was reported in 40% of patients, of whom 10% (4% total) had a persistent improvement at 3 months. Most of the studies in this systematic review had less than 50 patients, the quality of the evidence included in the meta-analysis was not described, and there was no assessment of potential publication bias.

Transcranial Random Noise Stimulation

Alashram et al. (2024) conducted a systematic review of studies on transcranial random noise stimulation for nonpulsatile tinnitus. (44) A total of 7 studies (N=616) were included in the review (4 randomized, 2 nonrandomized, and 1 one-arm pilot study). A meta-analysis was not performed, but the authors concluded that transcranial random noise stimulation (either single or multiple sessions) was effective in reducing tinnitus. Limitations included heterogeneity in study designs, a high risk of bias in 3 of the studies, and small sample sizes in some of the included studies.

Invasive Neuromodulation

Deklerck et al. (2019) conducted a systematic review of studies on invasive neuromodulation for tinnitus. (45) They identified 21 studies, which were mostly of low quality, with low sample sizes, lack of controls, or evaluating tinnitus as a secondary indication (e.g., the primary indication was movement disorders). Areas of stimulation included the caudate nucleus (2 reports), thalamus (2 reports), anterior cingulate (1 case report), dorsal cochlear nucleus (1 report), auditory cortex (7 reports), dorsolateral frontal cortex (1 case report), vestibulocochlear nerve (2 reports), C2 Dermatoma (1 case report) and vagus nerve (4 reports). The greatest number of studies and the studies with the largest population evaluated stimulation of the auditory cortex and were published between 2006 and 2014. Studies published within the previous 2 years focused on the dorsal cochlear nucleus, vestibulocochlear nerve, and vagus nerve.

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. (46) 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. (47) Only 2 (7%) of the 30 patients obtained a true-positive result.

Mielczarek and Olszewski (2014) reported on a placebo-controlled, nonrandomized trial of direct current electrical stimulation (DCS) of the ear in 120 patients (184 ears) with tinnitus and sensorineural hearing loss. (48) Directly after treatment, tinnitus improved in 37.8% of the active treatment group versus 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. (49) 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. Research on invasive neuromodulation for the treatment of tinnitus is at an early stage.

Transmeatal Laser Irradiation

Clinical Context and Therapy 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 individuals with tinnitus.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is 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. Commonly used self-report questionnaires include the THI, TQ, TFI, and the THQ as described above.

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.

Study Selection Criteria

- 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.

Randomized Controlled Trials

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, (50) in a 2009 placebo-controlled, double-blind, randomized trial with 60 patients, (51) a 2014 placebo-controlled, double-blind, randomized trial with 48 patients, (52) or a 2015 placebo-controlled, double-blind, randomized trial with 66 patients. (53)

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 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 behavioral therapies (CBTs) 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 CBT or acceptance and commitment therapy may also improve coping skills. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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. Two more recent RCTs evaluating notched music therapy for tinnitus found no significant differences in efficacy between this approach and ordinary music therapy or counseling. One additional RCT found tailor-made notched music therapy and tinnitus retraining therapy both improved tinnitus handicap inventory (THI) and visual analog scale (VAS) scores from baseline to 3 months follow-up, but the notched music therapy group had significantly improved THI scores at 1-month follow-up and VAS scores at 3 months follow-up compared to tinnitus retraining therapy. 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 that the technology results in an improvement in the net health outcome.

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 or tinnitus questionnaire scores) when tinnitus retraining therapy is compared with active or sham controls. For Heidelberg neuro-music 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. Another RCT found greater change in THI scores with sound therapy combined with CBT or structured counseling compared to sound therapy alone, but the number of patients in each group was small. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

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. (54) Table 7 provides some of the Academy's recommendations.

Table 7. Guidelines on Treatment of Tinnitus

Recommendation	SOR	GOE
"Clinicians must differentiate patients with bothersome tinnitus from patients with nonbothersome tinnitus"	Strong recommendation	B
"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	B
"Clinicians may recommend sound therapy to patients with persistent, bothersome tinnitus"	Option	C
"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	B

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

Medicare National Coverage

The Centers for Medicare & Medicaid Services had a longstanding national coverage determination for tinnitus masking, which was retired in 2014. (55)

Ongoing and Unpublished Clinical Trials

Some ongoing and unpublished trials that might influence this policy are listed in Table 8.

Table 8. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT06584175	Guided Internet-Delivered Cognitive Behavioural Therapy for Adults with Tinnitus in Canada: a Randomized Controlled Trial	82	Aug 2026
NCT06635967	The Efficacy of Repetitive Transcranial Magnetic Stimulation in Patients With Chronic Subjective Tinnitus	120	Dec 2025
NCT04551404	Transcranial Electrical and Acoustic Stimulation for Tinnitus: A Randomized Double Blind Clinical Trial	40	Dec 2025
NCT03511807	Acoustic and Electrical Stimulation for the Treatment of Tinnitus	100	Jun 2026
NCT04661995	Notched Noise Therapy for Suppression of Tinnitus: A Randomized Controlled Trial	108	May 2026
NCT06104865	Sound Therapy for Adults With Chronic Tinnitus, Using ((Resound Tinnitus Relief)) Mobile Application	100	Jul 2024 (unknown status)

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	90875, 90876, 90901, 92625, 92700, 0552T

HCPCS Codes	S8948

*Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
08/01/2026	Document updated. Coverage unchanged. References 6, 31, 33, 41, and 55 added.
06/15/2025	Document updated with literature review. Coverage unchanged. References 18, 20-22, and 40 added; others removed.
12/15/2024	Document updated with literature review. Coverage unchanged. Reference 17 added.
12/01/2023	Reviewed. No changes.
05/15/2022	Document updated with literature review. Coverage unchanged. References 4, 6, 7, 15, 16, 24, and 35 added, multiple references removed.
01/15/2022	Reviewed. No changes.
02/15/2021	Document updated with literature review. The following changes were made to Coverage: 1) Added "biofeedback (not done in conjunction with psychophysiological treatment" to list of experimental, investigational and/or unproven therapies; and 2) Clarified in the medically necessary statement that psychophysiological treatment may include biofeedback. The following references were added: 2-3, 5-6, 9-10, and 32-34; multiple references removed.
04/15/2019	Reviewed. No changes.
10/15/2018	Document updated with literature review. Coverage unchanged. References added 10-11, 33, and 42.
02/15/2018	Document updated with literature review. The following changes were made to Coverage: 1) Added "Psychological coping therapy (e.g., cognitive-behavior therapy [CBT], self-help CBT, tinnitus coping therapy, and acceptance and commitment therapy) may be considered medically necessary for persistent (duration ≥6 months) and bothersome tinnitus"; 2) Added "NOTE 1: Psychological therapies typically require 4 to 6 one-hour visits over an 18-month period"; 3) "Customized" added to "sound therapy" in list of experimental, investigational and/or unproven indications; 4) "Combined psychological and sound therapy" added as descriptor of tinnitus retraining therapy; 5) Added language to "see medical policy RX501.019" for injection of botulinum toxin.
09/15/2016	Document updated with literature review. The coverage statement was clarified to note the following: "Treatment of tinnitus with any non-pharmacologic or non-surgical modality is considered experimental, investigational and/or unproven, including but not limited to …" and the following was added to the listing of experimental, investigational and/or unproven indications: "Transcranial direct current stimulation".

07/15/2015	Reviewed. No changes.
06/15/2014	Document updated with literature review. The following indications added to the experimental, investigational and/or unproven listing: tinnitus coping therapy and sound therapy.
09/15/2011	Document updated with literature review. Coverage unchanged.
11/15/2009	Revised/updated entire document. No change in experimental, investigational and unproven coverage position.
11/15/2007	Revised/updated entire document.
11/01/2004	New CPT/HCPCS code(s) added
12/01/2003	Revised/updated entire document.
05/01/1993	Revised/updated entire document.
05/01/1990	New medical document