

NO. 91482

# TREATMENT OF TINNITUS

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**Policy scope:** This policy addresses the coverage determination for tinnitus retraining therapy (TRT) for the treatment of tinnitus.

**Related policies:**

- Hearing Augmentation No. 91544
- Biofeedback No. 91002

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## I. MEDICAL NECESSITY CRITERIA

**Inclusions:**

- A.** Management of chronic, subjective, bothersome tinnitus may be considered medically necessary when clinically appropriate and consistent with professional society guidelines, and **may** include:
1. Multidisciplinary tinnitus management programs emphasizing education, coping strategies, and shared decision-making.
  2. Comprehensive audiologic evaluation and patient education.
  3. Hearing aid evaluation and fitting for individuals with co-existing hearing loss.

4. Pharmacologic treatment of tinnitus (e.g. amitriptyline or other tricyclic antidepressants).

**Exclusions:**

**Not Medically Necessary as Considered Experimental and Investigational**

- A. The following management treatments for tinnitus have not been shown to be effective in peer reviewed medical literature. These approaches are considered investigational and unproven and are considered not medically necessary. These may include:
1. Acupuncture
  2. Biofeedback including the following:
    - a. Functional MRI (fMRI) Neurofeedback
  3. Brain Implant
  4. Cognitive Behavioral Therapy
  5. Combined psychological and sound therapy including:
    - a. Tinnitus retraining therapy (TRT)
  6. Deep Brain Stimulation (DBS)
  7. Neuromodulation including the following:
    - a. Transcutaneous electrical nerve stimulation (TENS)
    - b. Transcranial magnetic stimulation (TMS)
    - c. Repetitive transcranial magnetic stimulation (rTMS)
    - d. Theta-burst stimulation (TBS)
    - e. Transcranial direct current stimulation (tDCS)
  8. Psychedelic- Assisted Therapy
  9. Sound Therapy, including
    - a. Customized sound therapy
  10. Transmeatal laser irradiation

**Limitations:**

- A. Hearing aids are a covered benefit only if the Hearing Aid Rider is part of the member's contract.

**II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION**

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the [CMS Online Manual System \(IOMs\)](#) and Transmittals.

For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to [CMS Medicare Coverage Database](#).

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare [Coverage Database website](#) for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

**National Coverage Determinations (NCDs)**

Not Identified	
<b>Local Coverage Determinations (LCDs)</b>	
CGS Administrators, LLC	Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder (L36469)
First Coast Service Options, Inc.	Not Identified
National Government Services, Inc.	Transcranial Magnetic Stimulation (L33398) (DL33398)
Noridian Healthcare Solutions	Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder (L37086) (L37088)
Novitas Solutions, Inc.	Not Identified
Palmetto GBA	Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder (L34869)
WPS Insurance Corporation	Transcranial Magnetic Stimulation (TMS) (L34641)

### III. BACKGROUND

Tinnitus is the perception of sound, such as ringing, buzzing, or hissing—in the absence of an external acoustic stimulus. It is a common condition, affecting an estimated 14.4% of the global population, with approximately 2.3% experiencing severe or highly bothersome symptoms (Schoisswohl et al., 2025). Tinnitus is considered a symptom rather than a discrete disease entity and reflects underlying auditory or neurologic processes rather than a single pathologic mechanism.

While many individuals experience transient or non-bothersome tinnitus that does not require clinical intervention, a subset develop persistent, bothersome tinnitus associated with distress, sleep disturbance, impaired concentration, anxiety, or reduced quality of life. Chronic tinnitus is most commonly associated with sensorineural hearing loss but may also occur in individuals with audiometrically normal hearing (Tunkel et al., 2014).

Tinnitus is broadly categorized as subjective or objective, based on whether the perceived sound can be detected by an external observer. Subjective tinnitus is by far the most common form and is perceived only by the affected individual. It is typically associated with cochlear damage, auditory pathway dysfunction, sensorineural hearing loss, or idiopathic mechanisms. The majority of patients with chronic, bothersome tinnitus have subjective tinnitus, and most clinical research and management strategies are directed toward this population (Tunkel et al., 2014; Department of Veterans Affairs & Department of Defense [VA/DoD], 2024).

In contrast, objective tinnitus is rare and refers to tinnitus that can be detected by an examiner, either through auscultation or instrumentation. Objective tinnitus is usually

attributable to identifiable underlying conditions, such as vascular abnormalities (e.g., arteriovenous malformations or carotid artery disease) or muscular causes (e.g., palatal or middle-ear myoclonus). Management of objective tinnitus focuses on identification and treatment of the underlying cause rather than tinnitus-specific habituation or symptom-based therapies (Tunkel et al., 2014; National Institute for Health and Care Excellence [NICE], 2020).

### **Tinnitus Management**

Management of tinnitus depends on the type, severity, and associated clinical features. The primary approach involves evaluation and treatment of any underlying or contributing conditions, as well as strategies to mitigate the impact of tinnitus itself. Although there is no cure for most cases of chronic subjective tinnitus, management strategies aim to reduce distress, improve functional outcomes, and enhance quality of life. Medical management is therefore primarily directed toward individuals with chronic, subjective, bothersome tinnitus, for whom symptom-focused and supportive interventions may be considered.

Management interventions for tinnitus supported by major society guidelines and the broader literature emphasize education, reassurance, and management of comorbid conditions, rather than elimination of the tinnitus percept itself. For patients with hearing loss, hearing aids and sound amplification may reduce tinnitus perception and improve communication. Cognitive behavioral therapy (CBT) is consistently recommended to reduce tinnitus-related distress and improve quality of life, although it does not alter tinnitus loudness. Pharmacologic therapy is not recommended as a primary treatment for tinnitus; however, medications such as antidepressants, anxiolytics, or sleep agents may be considered when treating comorbid depression, anxiety, or insomnia, rather than tinnitus directly. In contrast, multiple interventions lack sufficient evidence to support routine clinical use, including transcutaneous electrical nerve stimulation (TENS), acupuncture, electrical or magnetic neuromodulation, and other complementary or alternative therapies. These approaches have not demonstrated consistent, durable, or clinically meaningful benefit in controlled trials and are generally classified as investigational or not recommended by clinical practice guidelines (Tunkel et al., 2014; NICE, 2020; VA/DoD, 2024).

### **Acupuncture**

Acupuncture is a traditional Chinese medicine technique that involves inserting fine needles into specific points on the body with the intent of modulating physiologic processes and relieving symptoms. Electroacupuncture (EA) is a variation in which a low-level electrical current is applied through the needles to provide continuous stimulation of selected acupuncture points.

A 2023 network meta-analysis evaluating acupuncture-based interventions for tinnitus across 36 randomized controlled trials involving 2,575 adults with idiopathic or primary tinnitus reported that some acupuncture and combination modalities were associated with higher response rates and statistically significant reductions in Tinnitus Handicap Inventory (THI) scores compared with conventional medical treatment alone (Ji et al., 2023). However, the evidence base was limited by substantial methodological weaknesses, including marked heterogeneity in acupuncture techniques and treatment protocols, variable use of co-interventions, short and inconsistent follow-up periods, reliance on subjective outcome measures without objective correlates, small sample

sizes for many comparisons, limited blinding and allocation concealment, and a high likelihood of nonspecific or placebo effects in a condition strongly influenced by psychological factors. Many treatment rankings were based on few trials, resulting in imprecision and unstable comparative estimates. Importantly, the authors noted that existing clinical practice guidelines do not recommend acupuncture for tinnitus due to insufficient high-quality evidence and emphasized the need for larger, well-designed randomized controlled trials with direct comparisons to establish durability of benefit and clinical relevance (Ji et al., 2023).

More recently, a multicenter, three-arm randomized controlled trial compared electroacupuncture (EA) and electroacupuncture combined with warm needling (EAWN) with a waitlist control in 90 adults aged 50–70 years with subjective tinnitus (Ho et al., 2025). Both active treatment groups demonstrated statistically significant short-term reductions in self-reported tinnitus loudness and THI scores at 5 and 10 weeks compared with waitlist; however, interpretation is limited by exclusive reliance on subjective outcomes, lack of participant and provider blinding, absence of a sham or attention-matched control, short follow-up insufficient to assess durability or relapse, restricted generalizability, and the absence of objective auditory or neurophysiologic endpoints. The authors acknowledged that longer-term, rigorously blinded trials incorporating objective measures are required to determine sustained clinical benefit (Ho et al., 2025).

Consistent with these findings, a systematic review and meta-analysis of randomized controlled trials found that acupuncture did not produce a statistically significant improvement in the primary outcome of tinnitus severity measured by visual analogue scale (VAS) compared with sham acupuncture, conventional treatment, or no treatment, with only modest improvements observed in secondary, patient-reported outcomes such as THI and Tinnitus Severity Index (TSI) (Huang et al., 2021). The overall quality of evidence was judged to be low due to small sample sizes, heterogeneity, and methodological limitations, precluding definitive conclusions regarding clinical effectiveness (Huang et al., 2021).

Taken together, current evidence does not demonstrate consistent, durable, or clinically meaningful net health benefit of acupuncture for tinnitus beyond established management strategies. Accordingly, acupuncture for the treatment of tinnitus is considered not medically necessary.

### **Biofeedback**

Biofeedback is a behavioral intervention that uses electronic monitoring to provide patients with real-time information about physiologic processes (e.g., muscle tension, heart rate, or skin conductance) with the goal of promoting voluntary self-regulation. In the context of tinnitus, biofeedback is intended to address stress-related or autonomic responses associated with symptom perception rather than the underlying auditory mechanism or the tinnitus percept itself.

A prospective randomized clinical trial comparing real-time functional MRI (fMRI) neurofeedback with cognitive behavioral therapy (CBT) in adults with chronic severe tinnitus reported greater reductions in tinnitus-related distress with fMRI neurofeedback at 6 and 12 months; however, the evidence was insufficient to establish medical necessity (Gninenko et al., 2024). The study was limited by a small sample size, substantial attrition at long-term follow-up, lack of blinding, and systematic differences

between treatment arms, including individualized, high-intensity fMRI neurofeedback versus group-based CBT, introducing performance and expectancy bias. Additional limitations included non-standardized neurofeedback protocols, potential confounding from baseline hearing differences, reliance on subjective patient-reported outcomes, and limited generalizability. Notably, fMRI neurofeedback is resource-intensive, requires specialized equipment and expertise, is not widely available in routine clinical practice, and is not endorsed by current clinical practice guidelines (Gninenko et al., 2024).

A subsequent 2026 neuroimaging study evaluating prolonged real-time fMRI neurofeedback in individuals with moderate-to-severe chronic tinnitus demonstrated changes in auditory cortex activity and reduced functional connectivity with the parietal operculum (OP3), a region implicated in multisensory integration (Gninenko et al., 2026). While these findings provide mechanistic insight into potential neural correlates of tinnitus and auditory downregulation, the study was not designed to evaluate clinical efficacy, relied on a small sample size, lacked a sham-controlled or blinded comparator arm, and focused primarily on exploratory neurophysiologic outcomes rather than validated patient-centered endpoints. The intervention required prolonged individualized training, highly specialized equipment, and significant technical expertise, further limiting scalability and real-world applicability (Gninenko et al., 2026).

Overall, biofeedback-based interventions, including fMRI neurofeedback, have not demonstrated consistent, durable, or clinically meaningful benefit for tinnitus outcomes, and current evidence remains insufficient to support their routine clinical use for tinnitus management.

### **Brain implants**

Brain implants, including brain–computer interface (BCI) technologies being developed by companies such as Neuralink, represent a highly experimental and speculative approach to the treatment of neurologic disorders, with only theoretical relevance to tinnitus at this time. These devices aim to establish a direct interface between neural tissue and external systems to monitor and modulate brain activity, which in theory could be used to influence abnormal neural signaling implicated in tinnitus perception. However, no brain implant has been approved or clinically studied for the treatment of tinnitus, and current research is limited to early animal studies and preliminary human trials for other neurologic conditions such as paralysis, epilepsy, and depression. Significant safety, ethical, and technical concerns remain, including the risks associated with intracranial surgery and the unknown long-term effects of chronic brain implantation. As such, brain implants remain investigational and are not considered a viable or established treatment option for tinnitus at this time (American Tinnitus Association, 2026).

### **Cognitive Behavioral Therapy (CBT)**

Cognitive Behavioral Therapy (CBT) is a structured, skills-based psychotherapy that targets patients' cognitive and emotional responses to tinnitus rather than the underlying auditory symptom. As CBT does not treat the physiologic cause of tinnitus or directly alter tinnitus perception, it is considered supportive in nature and is not medically necessary as a medical treatment for tinnitus itself.

Multiple systematic reviews and evidence syntheses consistently conclude that cognitive behavioral therapy (CBT) for tinnitus is associated with reductions in tinnitus-related distress and improved coping, but does not improve tinnitus loudness, perception, or

underlying auditory pathology. A Cochrane systematic review of randomized controlled trials found that CBT reduced tinnitus distress compared with no treatment or usual care; however, the authors emphasized that CBT does not target the tinnitus sound itself and that evidence regarding long-term durability of benefit and optimal delivery methods remains uncertain, with substantial heterogeneity across studies (Fuller et al., 2020). Similarly, an updated narrative synthesis of tinnitus guidelines and their evidence base reported that CBT is supported only for management of tinnitus-related psychological distress, with low-to-moderate certainty evidence and no demonstrated effect on tinnitus severity or cure (Langguth et al., 2023).

A randomized controlled trial evaluating cognitive behavioral therapy (CBT) for chronic subjective tinnitus demonstrated short-term improvements in tinnitus-related distress and self-reported symptom severity compared with no treatment. However, the study is limited by a small sample size (n=30), single-center recruitment, lack of an attention-matched or active control group, reliance exclusively on subjective self-reported outcomes, absence of treatment-fidelity assessment, and no long-term follow-up to evaluate durability of benefit. As CBT does not alter the underlying auditory mechanisms of tinnitus and observed improvements may reflect nonspecific effects such as therapist attention or expectancy, the evidence is insufficient to establish sustained clinical benefit attributable to CBT for tinnitus (Bal, 2025).

Guideline-aligned reviews further reinforce this distinction. The National Institute for Health and Care Excellence (NICE) concluded that CBT may be offered to reduce tinnitus-related distress but specifically noted the absence of evidence supporting improvement in tinnitus perception or auditory function and advised against interpreting CBT as a disease-modifying therapy (NICE, 2020). Likewise, the U.S. Department of Veterans Affairs and Department of Defense (VA/DoD) Clinical Practice Guideline characterizes CBT as a supportive intervention to address comorbid distress, anxiety, or functional impairment, while explicitly noting that CBT does not treat tinnitus itself and should not be considered curative or restorative of auditory function (VA/DoD, 2024).

Across these reviews, common limitations include reliance on subjective outcome measures, inconsistent follow-up duration, variability in CBT format (individual, group, or internet-based), and difficulty separating treatment-specific effects from nonspecific factors such as therapist attention, expectancy, or habituation. Collectively, the literature supports CBT only as a distress-modulating, coping-focused intervention, rather than a medically necessary treatment that addresses the underlying tinnitus symptom or provides consistent, durable clinical benefit.

### **Deep Brain Stimulation (DBS)**

Deep Brain Stimulation (DBS) is a highly experimental and invasive neurosurgical approach that has been explored in a limited number of cases for severe, intractable tinnitus. DBS involves the surgical implantation of electrodes into specific brain regions implicated in tinnitus processing, such as the thalamus or auditory cortex, with the goal of modulating abnormal neural activity. This approach is extrapolated from the established use of DBS in movement disorders such as Parkinson's disease and, more recently, in certain cases of treatment-resistant depression. Although isolated case reports and small exploratory studies have suggested potential tinnitus symptom reduction in select patients, the evidence remains extremely limited. DBS carries substantial surgical, neurologic, and neuropsychiatric risks, and long-term effects in tinnitus populations are not well understood. Consequently, DBS remains investigational and is not an established or routinely recommended treatment for tinnitus (Langguth et al. 2023; American Tinnitus Association, 2026).

## **Neuromodulation for Tinnitus**

Neuromodulation refers to therapeutic techniques that use targeted electrical, magnetic, or sensory stimulation to alter neural activity within specific brain or nerve pathways. In tinnitus, neuromodulation is intended to influence abnormal auditory or non-auditory neural signaling thought to contribute to tinnitus perception or distress, rather than directly eliminating the tinnitus sound itself.

**Transcutaneous Electrical Nerve Stimulation (TENS)** is a non-invasive therapy that delivers low-voltage electrical currents through surface electrodes placed on the skin to stimulate peripheral nerves. In tinnitus, TENS is typically applied to regions such as the cervical area or around the ear with the intent of modulating somatosensory input and related neural pathways that may influence tinnitus perception or distress.

Non-invasive electrical stimulation therapies, including transcutaneous electrical nerve stimulation (TENS) and other neuromodulation approaches, have been investigated for the treatment of subjective tinnitus based on their proposed ability to modulate neural activity within auditory and non-auditory pathways (Chen et al., 2023).

A 2024 systematic review and meta-analysis of sham-controlled randomized controlled trials evaluated multiple neuromodulation modalities, including TENS, transcranial direct current stimulation (tDCS), repetitive transcranial magnetic stimulation (rTMS), and theta burst stimulation (Heiland et al., 2024). While modest short-term reductions in tinnitus-related handicap as measured by the Tinnitus Handicap Inventory (THI) were observed—most notably with TENS and tDCS and limited longer-term effects with rTMS—treatment effects were inconsistent across outcome measures and frequently failed to meet thresholds for clinically meaningful improvement in tinnitus loudness, distress, or quality of life. Interpretation was further limited by substantial heterogeneity in stimulation techniques, treatment parameters, anatomic targets, session frequency, follow-up duration, and outcome reporting, as well as underpowered subgroup analyses. Several neuromodulation techniques could not be evaluated due to the absence of sham-controlled trials, and observed benefits were generally small, raising concerns regarding durability and incremental benefit beyond placebo effects. Collectively, these findings do not demonstrate consistent, durable, or clinically meaningful benefit sufficient to establish medical necessity for neuromodulation therapies in tinnitus management (Heiland et al., 2024).

A systematic review and random-effects meta-analysis of seven randomized controlled trials involving 342 adults with subjective tinnitus found that TENS was associated with a modest reduction in tinnitus-related handicap measured by THI (mean difference  $-8.60$  points) compared with sham or active controls; however, substantial heterogeneity was observed ( $I^2 = 62\%$ ), and no significant improvement was demonstrated in tinnitus loudness or annoyance as measured by visual analog scales (Shen et al., 2026). The overall certainty of evidence was rated as very low due to study limitations, heterogeneity, imprecision, and risk of bias (Shen et al., 2026).

In a placebo-controlled trial evaluating cervical TENS in adults with chronic somatic tinnitus associated with neck pathology and idiopathic chronic subjective tinnitus, short-term improvements in THI scores and selected quality-of-life domains were observed following four weeks of treatment (Soylemez et al., 2025). However, treatment effects were limited to short-term outcomes, anxiety measures improved inconsistently,

and interpretation was constrained by small sample sizes, brief follow-up, and heterogeneity across outcome measures. The authors characterized the study as exploratory and emphasized uncertainty regarding long-term efficacy, durability of benefit, and optimal patient selection.

Across the broader body of literature, small, randomized trials, pilot studies, and observational reports evaluating electrical stimulation–based interventions for tinnitus have produced inconsistent results. Common limitations include small sample sizes, non-standardized stimulation parameters, variable outcome measures, short follow-up periods, and limited reproducibility of findings, contributing to ongoing uncertainty regarding sustained clinical benefit (Chen et al., 2023).

Contemporary evidence syntheses similarly characterize electrical stimulation–based interventions for tinnitus as investigational and emphasize the need for well-designed, adequately powered randomized controlled trials with standardized protocols to establish clinical effectiveness and comparative benefit relative to established behavioral and sound-based management strategies (Chen et al., 2023).

Contemporary evidence syntheses and clinical practice guidelines uniformly characterize electrical stimulation–based neuromodulation therapies for tinnitus as investigational. Major professional societies, including the American Academy of Otolaryngology–Head and Neck Surgery Foundation, the U.S. Department of Veterans Affairs and Department of Defense, and the National Institute for Health and Care Excellence, do not endorse non-invasive electrical stimulation therapies as standard management for tinnitus and cite insufficient, inconsistent evidence to support their routine clinical use (Tunkel et al., 2014; VA/DoD, 2024; NICE, 2020).

**Transcranial Magnetic Stimulation (TMS)** is a non-invasive neuromodulation technique that uses rapidly changing magnetic fields applied over the scalp to induce electrical currents in targeted cortical regions. In tinnitus, TMS is intended to modulate abnormal neural activity within auditory and associated brain networks thought to contribute to tinnitus perception or distress, rather than directly eliminating the tinnitus sound itself.

The American Academy of Otolaryngology - Head and Neck Surgery Foundation’s clinical practice guideline on "Tinnitus" (2014) stated that clinicians should not recommend transcranial magnetic stimulation (TMS) for the treatment of patients with persistent, bothersome tinnitus.

**Repetitive Transcranial Magnetic Stimulation (rTMS)** is a non-invasive neuromodulation technique in which repeated magnetic pulses are delivered over specific scalp locations to induce electrical currents in targeted cortical regions. In tinnitus, rTMS is used with the intent of modulating abnormal neural activity within auditory and associated non-auditory brain networks that are thought to contribute to tinnitus perception or tinnitus-related distress, rather than eliminating the tinnitus sound itself.

Dong et al. (2020) conducted a systematic review and meta-analysis of randomized controlled trials evaluating low-frequency repetitive transcranial magnetic stimulation (rTMS) for the treatment of chronic tinnitus. The analysis included sham-controlled RCTs

assessing tinnitus severity, handicap, and loudness outcomes. Across pooled analyses, rTMS was not associated with consistent or clinically meaningful improvement in tinnitus severity or disability compared with sham stimulation. While some individual studies reported short-term benefit on select subjective measures, overall effect sizes were small and inconsistent, and improvements were not sustained across follow-up periods.

Interpretation of these findings is limited by heterogeneity in stimulation parameters, cortical targets, treatment duration, outcome instruments, and follow-up length, as well as generally small sample sizes and variable study quality. The authors concluded that existing evidence does not sufficiently support the routine clinical use of low-frequency rTMS for chronic tinnitus and emphasized the need for larger, well-designed randomized trials with standardized protocols to clarify efficacy and durability of benefit (Dong et al. 2020). Overall, this meta-analysis reinforces other contemporary evidence syntheses demonstrating that rTMS has not shown consistent, durable, or clinically meaningful benefit for tinnitus outcomes sufficient to support routine clinical adoption.

An updated meta-analysis of randomized, sham-controlled clinical trials evaluated the efficacy of repetitive transcranial magnetic stimulation (rTMS) for the treatment of tinnitus (Yin et al., 2021). Twelve trials involving 717 participants were included. Active rTMS was associated with statistically significant improvements in tinnitus-related handicap as measured by the Tinnitus Handicap Inventory (THI) in both short-term follow-up and at six months compared with sham stimulation; however, no significant immediate effect was observed. In contrast, rTMS did not demonstrate significant immediate improvement in tinnitus questionnaire (TQ) scores or depressive symptoms as measured by the Beck Depression Inventory (BDI), indicating limited impact on broader psychological or quality-of-life domains.

Interpretation of these findings is limited by variability in stimulation protocols, treatment parameters, cortical targets, and outcome measures across included trials, as well as inconsistent definitions of short- and long-term follow-up. While improvements in THI scores were observed, effect sizes were modest, and the clinical significance and durability of benefit remain uncertain. The authors emphasized the need for larger, multicenter randomized trials with standardized protocols and longer follow-up to clarify sustained clinical effectiveness. Overall, the evidence suggests that rTMS may produce limited improvements in tinnitus-related handicap in some patients but does not demonstrate consistent or comprehensive benefit across tinnitus severity, loudness, or associated psychological outcomes (Yin et al., 2021).

Kyong et al. (2024) investigated whether modulation of cortical alpha-band activity could serve as a neurophysiologic marker associated with tinnitus alleviation following neuromodulation. Using electroencephalographic (EEG) analysis in patients with tinnitus undergoing rTMS-based interventions, the study reported an association between changes in alpha power and reductions in tinnitus-related distress, suggesting that alpha-band modulation may reflect neural mechanisms involved in symptom improvement and could have potential value as a predictor of treatment response. The authors proposed that increased alpha activity may represent reduced cortical hyperexcitability and improved inhibitory control within tinnitus-related neural networks.

However, the findings are exploratory and subject to important limitations. The study was not designed to establish clinical effectiveness, relied on a relatively small sample size,

and focused on neurophysiologic correlates rather than durable, patient-centered clinical outcomes. EEG-based biomarkers were examined as associative predictors rather than validated endpoints, and the study did not establish thresholds for clinically meaningful change or demonstrate consistency across broader tinnitus populations (Kyong et al. (2024). As such, while the results provide mechanistic insight into potential neural correlates of tinnitus modulation, they do not demonstrate sustained clinical benefit or support routine clinical use of rTMS or EEG-guided neuromodulation strategies for tinnitus management.

**Transcranial Direct Current Stimulation (tDCS)** is a non-invasive neuromodulation technique that delivers low-intensity electrical currents through scalp electrodes to alter cortical excitability in targeted brain regions. In tinnitus, tDCS is applied with the intent of modulating abnormal neural activity within auditory and associated cortical networks thought to contribute to tinnitus perception or related distress, rather than directly eliminating the tinnitus sound itself.

A double-blind, randomized, sham-controlled clinical trial evaluated the short- and intermediate-term effects of anodal transcranial direct current stimulation (a-tDCS) targeting the left temporoparietal area (LTA) in 42 adults with tinnitus. Participants received either active a-tDCS (2 mA for 20 minutes over five consecutive days) or sham stimulation, with outcomes assessed using tinnitus severity, annoyance, loudness, hearing measures, and validated questionnaires including the Tinnitus Handicap Inventory (THI), Tinnitus Functional Inventory (TFI), and visual analogue scales (VAS). The study found no significant differences between active and sham groups across tinnitus severity, annoyance, loudness, or objective hearing measures at post-treatment or 30-day follow-up. A transient reduction in THI scores was observed only within the sham group immediately after treatment, with no sustained improvement at follow-up, indicating a likely placebo or nonspecific time effect (Martins et al. 2024).

Interpretation is limited by the small sample size, short treatment duration, and limited follow-up. Importantly, the absence of between-group treatment effects across primary tinnitus outcomes suggests that short-course a-tDCS targeting the LTA does not provide clinically meaningful benefit for tinnitus severity, annoyance, or loudness. The authors concluded that this tDCS protocol is ineffective for tinnitus management and that further research would need to explore alternative stimulation parameters or combination approaches (Martins et al. 2024). Overall, these findings are consistent with broader evidence indicating insufficient and inconsistent benefit of tDCS for tinnitus outcomes.

Leaver (2025) evaluated the perceptual and cognitive effects of focal transcranial direct current stimulation (tDCS) targeting the auditory cortex in adults with chronic tinnitus. Using a randomized, sham-controlled design, the study assessed auditory perception and cognitive performance before and after multi-session auditory-cortex tDCS. The results demonstrated that tDCS did not significantly worsen hearing thresholds or general cognitive function, supporting short-term tolerability of the stimulation protocol. However, subtle changes in cognitive task performance suggested that auditory-cortex tDCS may interfere with certain learning or practice-related effects, rather than providing broad cognitive benefit.

Importantly, the study was not designed to evaluate clinical efficacy for tinnitus outcomes and did not demonstrate improvement in tinnitus severity, loudness, or tinnitus-related

distress. Interpretation is limited by the modest sample size, short follow-up duration, and focus on perceptual and cognitive side effects rather than validated tinnitus-specific clinical endpoints (Leaver, 2025). As with other tDCS studies in tinnitus, findings primarily provide mechanistic and safety information and do not establish durable, clinically meaningful benefit for tinnitus management.

**Theta-Burst Stimulation (TBS)** is a form of repetitive transcranial magnetic stimulation that delivers brief bursts of high-frequency magnetic pulses patterned to mimic natural theta rhythms in the brain. In tinnitus, TBS is applied with the intent of modulating cortical excitability within auditory and associated neural networks to influence tinnitus perception or tinnitus-related distress, rather than eliminating the tinnitus sound itself.

Hong et al. (2021) conducted a randomized, sham-controlled pilot study evaluating the safety and effectiveness of multiple daily rounds of continuous theta-burst stimulation (cTBS) for chronic tinnitus. Fifteen adults were randomized to receive either active or sham stimulation over five consecutive days, with the active group receiving an intensified protocol (eight sessions per day, 2,400 pulses/day). Outcomes included tinnitus annoyance, duration, tinnitus loudness and pitch, minimum masking level, residual inhibition, visual analog scale (VAS) scores, and the Tinnitus Handicap Inventory (THI), assessed at baseline, immediately post-treatment, and at 1–3-month follow-up. While the intensified cTBS protocol was completed without adverse events, no statistically significant therapeutic effect was observed in tinnitus severity, loudness, annoyance, or THI scores in the active treatment group compared with sham.

Interpretation of these findings is limited by the small sample size, exploratory design, short treatment duration, and limited follow-up, which restrict statistical power and generalizability. The authors cautioned that the absence of observed clinical benefit may reflect insufficient sample size rather than treatment efficacy and emphasized the need for larger, well-designed trials to determine effectiveness. Overall, this study suggests that while intensified TBS protocols may be feasible and well tolerated, current evidence does not demonstrate clinically meaningful benefit for tinnitus outcomes, reinforcing the characterization of TBS as investigational in tinnitus management (Hong et al. 2021).

**Psychedelic-Assisted Therapy** is an emerging and experimental area of interest in tinnitus management, particularly for individuals whose tinnitus is closely associated with severe distress, anxiety, depression, or trauma. Compounds such as psilocybin and MDMA are under investigation for their potential to promote neural plasticity, emotional processing, and reorganization of maladaptive cognitive and affective responses to tinnitus. Evidence to date is limited to anecdotal reports and small exploratory studies, primarily extrapolated from research in conditions such as post-traumatic stress disorder, treatment-resistant depression, and substance use disorders. These interventions are administered only in tightly controlled clinical research settings, with structured psychological support before and after dosing. Psychedelic-assisted therapy carries significant psychological and medical risks—particularly for individuals with a personal or family history of psychotic or bipolar disorders—and remains investigational and legally restricted in many jurisdictions. At present, psychedelic-assisted therapy is not an established or recommended treatment for tinnitus and remains an area of early-stage research (American Tinnitus Association, 2026).

## **Sound therapy**

Sound therapy for tinnitus uses external sound (e.g., broadband noise, environmental sounds, or tinnitus-matched/modified sounds delivered via sound generators or hearing aids) to reduce tinnitus awareness and/or tinnitus-related distress, often by decreasing contrast between tinnitus and silence and supporting habituation.

Sound therapy for tinnitus including masking devices, wearable sound generators, tinnitus-matched or modified sounds (e.g., notched music), and proprietary systems such as the Otoharmonics Levo System has been evaluated across multiple randomized trials, systematic reviews, and professional guidelines, with heterogeneous and inconsistent results. High-quality evidence does not demonstrate consistent, durable, or clinically meaningful improvement in tinnitus loudness, severity, or quality of life when sound therapy is used as a standalone intervention, and between-group differences are often small or comparable to placebo or usual care.

A Cochrane systematic review evaluating sound therapy delivered through amplification devices and/or sound generators found that available trial data did not demonstrate consistent improvements in tinnitus loudness or overall tinnitus severity compared with other approaches such as counseling, education, relaxation, coping strategies, or tinnitus retraining–based interventions, and concluded that evidence remains limited due to few trials and methodological limitations (Sereda et al. 2018). Notably, although published in 2018, the review’s underlying evidence base reflects older randomized trials and highlights the ongoing lack of high-quality studies isolating sound therapy as a standalone intervention.

Major guidelines reflect this uncertainty: the NICE guideline concluded that recommendations could not be made due to insufficient evidence of clinical and cost-effectiveness (NICE,2020); the AAO-HNSF guideline allows sound therapy only as an optional management strategy without endorsing any specific modality (Tunkel et al., 2014); and the VA/DoD (2024) guideline characterizes therapeutic use of sound as supportive self-care (*Weak For*), while finding insufficient evidence for altered or customized music therapies (*Neither For Nor Against*). Given the lack of evidence establishing sound therapy as disease-modifying or superior to other management strategies, and the reliance on subjective outcomes with variable durability, sound therapy—including customized and device-based systems—is considered not medically necessary for the treatment of tinnitus.

### **Tinnitus Retraining Therapy (TRT)**

Tinnitus Retraining Therapy (TRT) is a structured management approach based on the neurophysiological model of tinnitus originally proposed by Jastreboff and colleagues. TRT is intended to reduce tinnitus-related distress by promoting habituation to the tinnitus percept rather than eliminating or modifying the tinnitus signal itself. The intervention consists of two core components:

- **Directive counseling**, which provides education regarding tinnitus mechanisms and seeks to reclassify tinnitus as a neutral, non-threatening stimulus; and
- **Sound therapy**, typically delivered through wearable sound generators or hearing aid–like devices set below the level of complete masking, with the goal of facilitating auditory habituation over time.

TRT protocols are generally delivered over extended periods, often 12 to 18 months, with repeated counseling sessions and daily sound enrichment. Substantial variation

exists in counseling intensity, device type, sound exposure parameters, and treatment duration, contributing to heterogeneity across clinical studies (Alashram, 2025).

Professional society guidelines consistently emphasize interventions aimed at reducing tinnitus-related distress and improving functional outcomes rather than eliminating tinnitus itself. The American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) clinical practice guideline recommends patient education, and hearing aid evaluation for individuals with hearing loss. While sound therapy may be considered as an option, the guideline does not identify TRT as a standard or preferred treatment modality (Tunkel et al., 2014).

The American Academy of Audiology recognizes TRT as one of several possible management approaches within audiologic practice but places it within a broader multidisciplinary framework that includes counseling, sound therapy, and behavioral strategies, without asserting evidence of superiority over alternative approaches (American Academy of Audiology, 2001). Similarly, the VA/DoD Clinical Practice Guideline for Tinnitus describes TRT as one form of sound enrichment combined with tinnitus-directed education, alongside other interventions such hearing aids, and progressive tinnitus management, emphasizing shared decision-making rather than endorsing TRT as superior (VA/DoD, 2024). Internationally, the National Institute for Health and Care Excellence (NICE) prioritizes assessment, education, and stepped care and does not recommend TRT as a distinct standard-of-care intervention (NICE, 2020).

Across U.S. and international guidelines, TRT is acknowledged as a potential management approach but is not endorsed as a standard, preferred, or superior treatment compared with other evidence-supported strategies.

Earlier critiques of TRT noted a lack of high-quality randomized controlled trials. Although more recent studies and systematic reviews are available, findings remain mixed and inconclusive. A large multicenter randomized clinical trial with 18-month follow-up found that TRT using conventional sound generators did not result in clinically meaningful improvements in tinnitus-related quality of life compared with TRT using placebo sound generators or standard care alone (Erdman et al., 2019).

A 2025 systematic review of randomized controlled trials evaluated TRT across multiple tinnitus-related outcomes, including severity, distress, sleep, and quality of life. While some patients demonstrated improvement from baseline, there was no consistent evidence that TRT was superior to alternative interventions such as tinnitus masking, educational counseling, usual care, or partial TRT. Considerable variability in study design, outcome measures, and TRT protocols limited conclusions regarding long-term comparative effectiveness (Alashram, 2025).

In a randomized, single-blinded controlled trial comparing tailor-made notched music training (TMNMT) with TRT, both interventions were associated with short-term improvement in tinnitus outcomes over a three-month intervention. TMNMT demonstrated greater reductions in tinnitus handicap (THI) and tinnitus loudness (VAS), with between-group differences approaching clinical significance (Tong et al., 2023). However, interpretation was limited by deviations from conventional TRT protocols, short treatment duration, reliance on subjective outcome measures, single-center design,

potential floor effects from low baseline THI scores, and lack of standardization within the TMNMT intervention (Tong et al., 2023).

A 2024 network meta-analysis of 22 randomized controlled trials involving 2,354 patients evaluated multiple non-invasive tinnitus treatments, including acceptance and commitment therapy (ACT), CBT, sound therapy, TRT, neuromodulation techniques, and placebo. Effectiveness varied by outcome domain. CBT ranked highest for tinnitus-related distress and questionnaire-based severity measures, sound therapy ranked highest for tinnitus handicap and loudness outcomes, and ACT ranked highest for anxiety, depression, and insomnia. TRT demonstrated comparatively lower effectiveness, particularly for insomnia outcomes (Lu et al., 2024). The analysis highlighted significant heterogeneity across outcome measures and interventions and underscored the absence of a single universally effective non-invasive therapy (Lu et al., 2024).

TRT is a structured counseling and sound-based habituation approach that is recognized in clinical practice but has not been established as a standard or superior treatment for tinnitus. Current professional society guidelines prioritize education, behavioral interventions, and hearing rehabilitation when clinically appropriate. Contemporary evidence syntheses continue to demonstrate uncertainty regarding the incremental clinical benefit of TRT relative to other management strategies, and available data do not support TRT as a preferred or definitive intervention for tinnitus management.

### **Transmeatal laser irradiation**

Transmeatal laser irradiation is a non-invasive therapy that delivers low-level laser energy through the external auditory canal toward the middle or inner ear structures. In tinnitus, it has been proposed to influence cochlear metabolism or neural activity; however, it does not directly target the underlying auditory pathology or eliminate the tinnitus percept itself.

A prospective, double-blind, randomized, placebo-controlled trial evaluated the effectiveness of transmeatal low-power laser stimulation (TLLS) for the treatment of persistent subjective tinnitus. Participants were randomized to active TLLS (5 mW, 650 nm wavelength, 20 minutes daily for 10 weeks) combined with oral betahistine or to a placebo device combined with equivalent betahistine therapy. Tinnitus outcomes were assessed using the Tinnitus Handicap Inventory (THI) and visual analogue scale (VAS) measures before and after treatment. Although both treatment and placebo groups demonstrated statistically significant improvements from baseline in THI and VAS scores, no statistically significant differences were observed between the active TLLS and placebo groups across tinnitus severity, annoyance, sleep disturbance, concentration, mood, or tinnitus loudness and pitch. The observed improvements were therefore attributed to nonspecific or placebo effects rather than a treatment-specific benefit of laser therapy.

Interpretation of these findings is limited by modest sample size, reliance on subjective outcome measures, concomitant use of betahistine in both groups, and absence of objective auditory or neurophysiologic endpoints. Importantly, the lack of between-group differences indicates that transmeatal low-power laser stimulation did not demonstrate clinically meaningful efficacy as a therapeutic intervention for tinnitus. Overall, this study

supports the conclusion that transmeatal laser irradiation has not been shown to provide consistent or incremental clinical benefit beyond placebo for tinnitus management.

**IV. GUIDELINES / POSITION STATEMENTS**

<b>Medical/Professional Society</b>	<b>Guideline</b>
National Institute for Health and Care Excellence (NICE)	<a href="#">Tinnitus: assessment and management</a> (2020)
Department of Veterans Affairs (VA)/Department of Defense (DoD)	<a href="#">VA/DoD Clinical Practice Guideline for Tinnitus</a> (2024)
American Academy of Otolaryngology- Head and Neck Surgery	<a href="#">Clinical Practice Guideline: Tinnitus</a> (2014)
American Academy of Audiology	<a href="#">Audiologic Guidelines for the Diagnosis and Management of Tinnitus Patients - American Academy of Audiology</a> (2001)

**V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)**

See [U.S. Food & Drug Administration \(FDA\) Medical Device Databases](#) for the most current information.

<b>Device</b>	<b>Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number</b>	<b>Decision date</b>
Otoharmonics Levo System	K140845	07/18/2014
Peace N Quiet	K233435	02/27/2024
Tinearity G1 (6103); Tinearity G1 Adapters X3 (6042)	K223694	06/30/2023
Tinnitogram Signal Generator	K221168	02/01/2023
Silentcloud	K221125	01/04/2023
Multiflex Tinnitus Technology	K201370	06/19/2020
Tinnitus Sound Generator Module	K193303	02/20/2020
Audifon Tinnitus- Module	K171243	10/19/2017
Tinnilogic Mobile Tinnitus Management De	K163094	05/17/2017
Sound Options Tinnitus Treatment	K161562	09/28/2016
Hypersound Tinnitus Module	K161331	08/23/2016

Desyncra For Tinnitus Therapy System, De	K151558	01/20/2016
Reve134	K151719	10/9/2015
Soundcure Serenade Tinnitus Treatment Sy	K150065	04/13/2015
Levo Tinnitus Masking Software Device	K140845	07/18/2014
Solace Sound Generators	K132965	03/25/2014
Tinnitus Sound support	K133308	03/18/2014
Wave 2g, Soul	K130937	01/03/2014

## VI. CODING

**See also Priority Health Medical Policy No. 91636 - Category III Current Procedural Terminology (CPT®) Codes (“T” codes)**

### ICD-10 Codes that apply to this policy:

H93.11	Tinnitus, right ear
H93.12	Tinnitus, left ear
H93.13	Tinnitus, bilateral
H93.19	Tinnitus, unspecified ear

### CPT/HCPCS Codes

92625            Assessment of tinnitus (includes pitch, loudness matching, and masking)

*Codes billed for treatments above are not covered (list not inclusive):*

92700	Unlisted otorhinolaryngological service or procedure
97039	Unlisted modality (specify type and time if constant attendance)
V5298	Hearing aid, not otherwise classified
V5299	Hearing service, miscellaneous
E1399	Durable medical equipment, miscellaneous

*Explanatory notes must accompany claims billed with these codes*

### Not Medically Necessary:

90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management
90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session
90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management
90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg,

	insight oriented, behavior modifying or supportive psychotherapy); 30 minutes
90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes
90901	Biofeedback training by any modality
0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes
0858T	Externally applied transcranial magnetic stimulation with concomitant measurement of evoked cortical potentials with automated report
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold-starting location, neuronavigation files and target report, review and interpretation
0890T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day
0892T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day

## VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the [Priority Health Provider Manual](#).

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a

chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

## VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO:** This policy applies to insured HMO/EPO plans.
- **POS:** This policy applies to insured POS plans.
- **PPO:** This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO:** For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL:** For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE:** Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN:** For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the [Michigan Medicaid Fee Schedule](#). If there is a discrepancy between this policy and the [Michigan Medicaid Provider Manual](#), the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

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## SUMMARY OF CHANGES

### Additions:

- Added evidence-supported management inclusions, such as patient education, audiologic evaluation, hearing aids when indicated, and pharmacologic treatment of comorbid conditions.
- Added a clear experimental/investigational exclusions list, including brain implant, CBT as a tinnitus treatment, sound therapy, neuromodulation, acupuncture, biofeedback, and other alternative or device-based therapies.
- Added structured sections for society guidelines, CMS considerations, and FDA context.

### Changes:

- Updated the policy title and structure to reflect a comprehensive tinnitus management framework.
- Expanded and updated the background and references to reflect current evidence and guidelines.

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**Past committee review dates:** 04/2004, 05/2004, 07/2005, 06/2006, 06/2007, 06/2008, 06/2009, 06/2010, 06/2011, 06/2012, 06/2013, 05/2014, 05/2015, 05/2016, 05/2017, 05/2018, 05/2018, 05/2019, 05/2020, 05/2021, 05/2022, 05/2023, 05/2024, 05/2025, 05/2026

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