

## FEP 8.01.39 Treatment of Tinnitus

**Effective Date:** April 15, 2018

**Related Policies:**

2.01.50 Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders  
2.01.56 Low Level Laser Therapy  
5.75.01 Botox

## Treatment of Tinnitus

### Description

Various nonpharmacologic treatments are being evaluated to improve the symptoms of tinnitus. These approaches include psychological coping therapies, sound therapies, combined psychological and sound therapies, repetitive transcranial magnetic stimulation, electrical and electromagnetic stimulation, and transmeatal laser irradiation.

### FDA REGULATORY STATUS

The Neuromonics® Tinnitus Treatment is one of many tinnitus maskers cleared for marketing by the U.S. Food and Drug Administration 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." Food and Drug Administration product code: K LW.

### POLICY STATEMENT

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

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

- tinnitus maskers, customized sound therapy
- combined psychological and sound therapy (eg, tinnitus retraining therapy)
- transcranial magnetic stimulation,
- transcranial direct current stimulation
- electrical transcutaneous electrical stimulation of the ear, electromagnetic energy
- transmeatal laser irradiation.

Note: This policy does not address surgical (eg, cochlear or brainstem implants) or pharmacologic (eg, use of amitriptyline or other tricyclic antidepressants) treatments of tinnitus, or injection of botulinum toxin.

### BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

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### RATIONALE

#### Summary of Evidence

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

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

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

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

For individuals who have tinnitus who receive electrical or electromagnetic stimulation, the evidence includes a number of sham-controlled randomized trials. Relevant outcomes are symptoms, functional

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outcomes, quality of life, and treatment-related morbidity. The available evidence does not currently support the use of these stimulation therapies. A 2015 sham-controlled study that was adequately powered found no benefit of transcranial direct current stimulation. Moreover, while a 2017 meta-analysis found some benefit for transcranial direct current stimulation, it was noted that further study would be needed to evaluate transcranial direct current stimulation as a treatment option. Studies have not shown a benefit for direct current electrical stimulation of the ear. The evidence on electromagnetic energy includes a small RCT, which found no benefit for the treatment of tinnitus. The evidence is insufficient to determine the effects of the technology on health outcomes.

### SUPPLEMENTAL INFORMATION

#### Practice Guidelines and Position Statements

##### International Federation of Clinical Neurophysiology

The International Federation of Clinical Neurophysiology sponsored evidence-based guidelines (2017) on the use of transcranial direct current stimulation (tDCS).<sup>42</sup> The guidelines did not recommend tDCS as a treatment for tinnitus, because studies suggested anodal tDCS of the left temporoparietal cortex was probably ineffective (level B evidence). A lack of data precluded any recommendation on use of tDCS of the left dorsolateral prefrontal cortex as therapy for chronic tinnitus.

##### American Academy of Otolaryngology – Head and Neck Surgeons

In 2014 the American Academy of Otolaryngology – Head and Neck Surgeons published evidence-based guidelines on tinnitus.<sup>43</sup> Table 1 provides some of the Academy's recommendations.

**Table 1: 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 should educate patients with persistent, bothersome tinnitus about management strategies"	Recommendation	B, C
"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	

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

#### U.S. Preventive Services Task Force Recommendations

Not applicable.

#### Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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### POLICY HISTORY

Date	Action	Description
December 2011	New Policy	
June 2012	Update Policy	Policy statement changed to not medically necessary. Related policies added. Additional background information added.
September 2013	Update Policy	Policy updated with literature search; references added and reordered;

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		policy statement unchanged.
June 2015	Update Policy	Policy updated with literature search. References 1, 5, 11, 22, 27, 38, 42-43, and 46 added; Policy statement is unchanged.
September 2016	Update Policy	Policy updated with literature review through December 10, 2015; references 14, 24-26, and 28 added; some references removed. Policy statement reordered and "surgical" added to the note on topics that the policy does not address.
March 2018	Update Policy	Policy updated with literature review through December 11, 2017; references 9-10, 17-18, 32, and 40-41 added. The policy statement revised to psychological coping therapy may be considered medically necessary for persistent and bothersome tinnitus. Combined psychological and sound therapy added to the investigational policy statement.

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