

# Kaiser Foundation Health Plan of Washington

# Clinical Review Criteria Tinnitus Masking/Retraining Therapy

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#### Criteria

#### For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Tinnitus Masking/Retraining Therapy" for medical necessity determinations. Use the Non-Medicare criteria below.

<sup>\*</sup>Codes for auditory assessment and rehabilitation are covered by Medicare.

#### For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies or provides better long-term outcomes than current standard services/therapies.

#### If requesting review for this service, please send the following documentation:

• Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

#### **Background**

Tinnitus is the perception of sound in the absence of an acoustic source (Luxon 1993). The perceived sound can vary from simple sounds such as whistling or humming to complex sounds such as music. Tinnitus may be perceived as a single sound or multiple sounds, unilateral or bilateral, within the head or outside the body, and intermittently or constantly. The American Tinnitus Association estimates that 50 million Americans have some degree of tinnitus with about 16 million of those experiencing significant enough symptoms to seek medical care and 2 million of them suffering so much that it ultimately interrupts normal day to day function. Tinnitus can occur at any age but its incidence increases by the age of 40 and peaks between 65 to 79 years (Hobson, Chisholm et al. 2012). The tinnitus experience is consistently higher among men and is strongly related to hearing loss but may be experienced by individuals with normal hearing as well. Acute tinnitus, which can last for days or weeks, may be caused by ear infection, medication, ear wax, exposure to excessive sound or changes in blood pressure. Chronic tinnitus, experienced by 10 to 15% of adults, persists for six or more months and may be caused by almost any disorder involving the outer, middle or inner ear, or the auditory nerve (Davis, Paki et al. 2007). In any 91998, Kaiser Foundation Health Plan of Washington. All Rights Reserved.

case, tinnitus can be debilitating because it is difficult to describe, predict and manage and can lead to disruption of sleep, inability to concentrate, and depression.

Tinnitus is not a condition itself, rather, it is a symptom of an underlying condition and, therefore, management should include diagnosis and elimination of the factors precipitating tinnitus. In many cases, the cause of tinnitus cannot be identified warranting treatment of the symptom itself. At present, no universal treatment has been found effective in all patients and options are heavily dependent on the severity and perception of the condition. Treatment might range from counseling and dietary modification to acupuncture and relaxation therapy. Optimal management techniques seek to minimize the detrimental effects on activities of daily life and might include a variety of strategies. The use of medications and surgical interventions are rarely successful.

Tinnitus masking instruments have been clinically employed for alleviating symptoms for decades. These devices are worn behind or in either the same or the opposite ear affected by tinnitus and generate a noise based on the principle of distraction. The idea being that the level of noise, usually white noise, is introduced and can reduce the contrast between the tinnitus signal and background activity in the auditory system, with a decrease in the patient's perception of their tinnitus (Vernon 1977). The characteristics and circumstances of the tinnitus determine the kind of masking noise and instruments that might bring relief. No side effects or significant morbidities have been reported, to date, from the use of maskers or hearing aids as treatment for tinnitus and no substantial risks of sound therapy have been demonstrated.

Tinnitus instruments such as maskers and hearing aids are approved by the Food and Drug Administration (2009) for alleviating the symptoms associated with tinnitus and are classified as a Class III device.

### **Medical Technology Assessment Committee (MTAC)**

Tinnitus Masking Devices 02/10/1999: MTAC Review

**Evidence Conclusion:** *Masking*: One small randomized controlled crossover study reports no decrease in self report of tinnitus intensity but statistically significant improvement in both specific and nonspecific effects of masking on tinnitus. Another study of patients randomized to masking or hearing aid devices and then allowed to choose which device to continue using demonstrated that 60% chose to continue using a masking device and 20% discontinued the use of any device. *Retraining Therapy*: A single small RCT demonstrated a statistically significant reduction (1-point improvement on a 10-point visual analogue scale) in subjective tinnitus loudness and discomfort following behavioral training as compared to a no treatment control group.

<u>Articles:</u> Erlandsson, S, et. Al. Treatment of Tinnitus: A Controlled Comparison of Masking and Placebo, British *J Audiol.* 1987, 21, 37-44. See <u>Evidence Table</u> Mehlum, D et. Al. Prospective Crossover Evaluation of Four Methods of Clinical Management of Tinnitus, *Otolaringol. Head Neck Surg.* 1984: 92: 448-453 See <u>Evidence</u> <u>Table</u> Scott, B. Et. Al. Psychological Treatment of Tinnitus: An Experimental Group Study. Scand. Audiol. 1985, 14: 223-230 See <u>Evidence Table</u>

The use of Tinnitus Masking Devices for treatment of tinnitus does not meet *Kaiser Permanente Medical Technology Assessment Criteria*.

## Tinnitus Masking Devices 6/17/2013: MTAC REVIEW

Evidence Conclusion: Henry et al 2006 study recruited 800 US military veterans via advertisements. Following screening, 172 candidates were enrolled into the study; those not eligible were not convinced that their tinnitus was sufficiently severe, or they were not motivated to comply with the study requirements. A further 49 subjects were excluded in secondary screening resulting in a total of one hundred and twenty-three patients commencing treatment. Candidates were quasi-randomly assigned to a tinnitus masking (TM) device or tinnitus retraining therapy group (TRT). The mean age in the sound therapy group was 61 (SD 9.6) and in the tinnitus retraining group it was 58.7 (SD 10.5). Baseline audiometry was performed and the Tinnitus Handicap Inventory (THI), Tinnitus Handicap Questionnaire (THQ) and Tinnitus Severity Index (TSI) were administered. Both groups used a combination of noise generators, hearing aids and combination instruments. Audiometry and questionnaires were evaluated at 3, 6, 12 and 18 months. The results show that for patients with 'moderate' problems, sound therapy resulted in a statistically significant improvement in the THQ at six months but tinnitus retraining therapy (TRT) appeared to offer superior results. For patients who described their tinnitus as a 'big' problem, there was an across the board significant improvement in the three instruments at all time points except three months, which is comparable to the TRT group. Looking at the effect sizes, for sound therapy these ranged from 0.18 to 0.59 in © 1998, Kaiser Foundation Health Plan of Washington. All Rights Reserved. Back to Top

the 'moderate group and did not show a systematic improvement over time. For those with a 'big' problem, the effect sizes for sound therapy ranged from 0.46 to 0.86 and whereas the THI and TSI improved over time the THQ effect size remained unchanged. For those with a 'very big' problem the effect of sound therapy seemed greater at three months, with a trend of effect sizes becoming progressively smaller through 18 months. Based on effect size, both groups showed considerable improvement overall but whereas the benefits of sound therapy tended to remain constant over time, the effect of tinnitus retraining improved incrementally. Currently, the literature on maskers and/or hearing aids for the treatment of tinnitus in adults is limited. First and foremost, the lack of an established universal tool for baseline and follow-up assessment of outcome measures restricts the ability to produce valid data and make comparisons. Additionally, due to the often "off label" use of hearing aids as tinnitus treatments there has been a dearth of driving forces for undertaking large randomized controlled trials. Henry and colleague's study demonstrate some of these limitations; although the study claims to be controlled. the two groups being investigated do not make an attempt to treat both groups similarly. Different instruments are used across the study, and even within each group, and patient contact time differs by 1.4 hours between the TM and TRT groups. In addition to these limitations, the study was quasi-randomized which allows for a greater risk of selection bias. The study also notes that the devices were more apt to break in the TRT group compared to the TM group and variation in treatment specialists for each method might result in clinician differences. While some of the studies included in the Cochrane Review report that patients experienced a decrease in tinnitus with use of masking devices there is no conclusive evidence to validate the effectiveness. On the whole, the studies included in the review demonstrate either no or limited improvement in tinnitus perception. Furthermore, the quality of the studies is, generally, low. With several different devices employed throughout the studies and marked methodological heterogeneity including numerous measures of evaluation of tinnitus severity and outcome all with different scores, scales, tests and questionnaires, comparisons and further analysis are complicated. Small sample sizes also contribute to the low quality leading to the inability to generalize findings. Conclusions: Although some patients report a decrease in tinnitus with the use of masking devices, there is no conclusive evidence from randomized trials to demonstrate effectiveness. The limited data from the included studies show that sound therapy on its own is of unproven benefit in the treatment of tinnitus, although the effect may be better than placebo. Thus far, no adverse outcomes or significant morbidity from using sound-generating (masking) devices have been reported, and furthermore, the literature is unable to demonstrate any substantial risks.

<u>Articles:</u> Henry JA, Schechter MA, Zaugg TL, Griest S, Jastreboff PJ, Vernon JA, Kaelin C, Meikle MB, Lyons KS, Stewart BJ. Clinical trial to compare tinnitus masking and tinnitus retraining therapy. *Acta Oto-Laryngologica*, 2006;126:64-69. <u>See Evidence Table</u>

The use of Tinnitus Masking Devices for treatment of tinnitus does not meet *Kaiser Permanente Medical Technology Assessment Criteria*.

## **Applicable Codes**

#### **Considered Not Medically Necessary:**

CPT®	Description
Codes	
92626	Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); first hour
92627	Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); each additional 15 minutes (List separately in addition to code for primary procedure)
92630	Auditory rehabilitation; prelingual hearing loss
92633	Auditory rehabilitation; postlingual hearing loss
ICD-10	Description
Codes	
H93.11- H93.19	Tinnitus-right ear, left ear, bilateral and unspecified

\*Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

<sup>\*\*</sup>To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

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Date Created	Date Reviewed	Date Last Revised
12/1998	04/04/2011 MDCRPC, 02/07/2012 MDCRPC, 12/04/2012 MDCRPC, 08/06/2013MPC, 06/03/2014MPC, 04/07/2015MPC, 02/02/2016MPC, 12/06/2016MPC, 10/03/2017MPC, 09/04/2018MPC, 09/03/2019MPC, 09/01/2020MPC, 09/07/2021MPC, 09/06/2022MPC, 09/05/2023MPC, 01/09/2024MPC	09/01/2020

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision	Description
History	
09/01/2020	Added KPWA Medical Policy statement under Medicare section