



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Tinnitus Treatment Services  
and Devices**

**Effective Date ..... 11/15/2010**  
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Electrical Stimulators  
Hearing Aids  
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## INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

## Coverage Policy

**CIGNA does not cover ANY of the following for the treatment of tinnitus, because each is considered experimental, investigational or unproven (this list may not be all-inclusive). In addition, many benefit plans specifically exclude some of the devices and services listed below:**

- non-wearable environmental maskers
- wearable masking devices and instruments
- white-noise or non-masking sound generators
- transcutaneous electrical nerve stimulation (TENS)
- transmeatal laser irradiation
- repetitive transcranial magnetic stimulation (rTMS)
- cognitive behavioral therapy
- tinnitus retraining therapy (TRT)
- hearing aids

- cochlear device implantation
  - hyperbaric oxygen therapy
- 

## General Background

Tinnitus, the perception of sound when no corresponding environmental sound exists, is equally common in men and women. Prevalence increases with age, but tinnitus occasionally affects children. While tinnitus is commonly reported, its pathophysiology is not well-understood. Postulated theories include (Fortune, et al., 1999):

- injured cochlear hair cells that discharge repetitively, stimulating auditory nerve fibers in a continuous cycle
- spontaneous activity in individual auditory nerve fibers
- hyperactivity of the auditory nuclei in the brainstem
- cochlear injury, resulting in reduction of the suppressive influence of the central auditory cortex on higher neuronal activity

There are no proven treatment options for tinnitus, except when a treatable underlying pathology has been identified. In essence, tinnitus is a symptom, rather than a condition or disease. It may or may not be associated with a conductive or sensorineural hearing loss. The presence of tinnitus may be the first symptom of a serious underlying problem, such as a vestibular schwannoma (i.e., acoustic neuroma), or it may be clinically benign. Individuals' descriptions of the impact of tinnitus on their daily lives range from slightly irritating to disabling. Lockwood et al. (2002) reported that the perceived severity of tinnitus is unrelated to measurements of its loudness and pitch.

Characterization of the perceived sound is integral to the evaluation of tinnitus. There is no standard protocol or consensus on tinnitus assessment and evaluation. The assessment of tinnitus should include a detailed history, clinical examination and audiometric evaluation. Some providers use tinnitus severity scales in their assessments. The Tinnitus Handicap Inventory (THI) is one example of self-assessment surveys used in some clinics. Basic tinnitus measurements employed by many providers include pitch and loudness matching. Tinnitus can be described as low- or high-pitched; loud or soft; buzzing or ringing; paroxysmal, transient or continuous. Distinguishing between objective and subjective tinnitus is essential to its successful diagnosis and subsequent management.

Objective tinnitus refers to internal sounds that may also be audible to an observer with a stethoscope or other auscultation device. Some individuals experience pulsatile tinnitus, rhythmic sounds that are closely associated with the heart rate. The most common causes of objective tinnitus include neuromuscular disorders, vascular abnormalities and abnormalities of the eustachian tube. Treatment of objective tinnitus is dictated by the identified underlying disorder.

Subjective tinnitus, the false perception of noise by an individual in the absence of acoustic stimulation of the cochlea, is far more common than objective tinnitus. Subjective tinnitus is a diagnosis of exclusion, made only after other possible conditions have been ruled out. The pathophysiology of subjective tinnitus is not well-understood. Symptoms may arise from a lesion at any point along the auditory pathway, including the external canal, tympanic membrane and auditory nerve. Other causes of subjective tinnitus include:

- otologic: noise-induced, presbycusis, impacted cerumen, otosclerosis, Ménière's disease
- neurological: head injury, vestibular schwannoma
- infectious: otitis media, meningitis
- drug-related: salicylates, loop diuretics, chemotherapeutic agents, nonsteroidal anti-inflammatories
- dental: TMJ (temporomandibular joint) and other disorders

Severe subjective tinnitus may be associated with other symptoms, such as hyperacusis and sound distortion. Psychological and psychosocial conditions, such as depression, phonophobia and social isolation may also accompany tinnitus.

Treatment of subjective tinnitus is supportive in nature, and no single treatment has been demonstrated to be effective through well-designed clinical trials. Proposed treatments include:

- pharmacotherapy (e.g., benzodiazepines, tricyclic antidepressants)
- tinnitus instruments and masking devices
- transcutaneous electrical nerve stimulation (TENS)
- repetitive transcranial magnetic stimulation (rTMS)
- transmeatal laser irradiation
- tinnitus retraining therapy
- cognitive therapy
- hypnosis
- psychotherapy
- counseling
- iontophoresis with lidocaine
- hyperbaric oxygen therapy (HBO or HBOT)

### **Masking Devices and Instruments**

Tinnitus masking devices have been proposed to treat the symptom of tinnitus. The aim of masking devices is to give the patient a perceived sense of relief from the tinnitus sound. A wearable tinnitus masker is a device designed to be worn behind the ear that produces external noise to distract the patient from perception of internal noise.

In general, tinnitus masking devices are approved by the FDA under the 510(k) process as Class II devices (some older models were approved as Class III devices). The TCI Tinnitus Control Instrument™ (Siemens Hearing Instruments, Piscataway, NJ) and HiSonic® -TRD Tinnitus Relief Device (Hearing Innovations, Inc., Tucson, AZ) are examples of behind-the-ear style tinnitus maskers.

Non-wearable or environmental devices have also been used in an attempt to mask tinnitus. These non-wearable devices may be referred to as "augmentative sound devices." Some of these products emit natural sound effects, such as rain, waterfall and surf; others use music. In addition to masking the tinnitus, many of these devices aim to produce relaxation.

TinniTech ANMP System (TinniTech LTD, Sydney, Australia), DTM-6a Dynamic Tinnitus Mitigation System™ (Petroff Audio Technologies, Palmdale, CA), Ultraquiet™ (Sound Technique Systems, LLC, Newport News, VA), and the Neuromonics Tinnitus Treatment System delivered via the Oasis™ (Neuromonic Pty Ltd, Chatswood, Australia) are FDA approved as Class II devices.

The term "tinnitus instrument" typically refers to a combination, wearable, ear-level device, consisting of a high-frequency hearing aid and a low-level noise generator within the same case. The TCI-Combi™ (Siemens Hearing Instruments, Piscataway, NJ) is a behind-the-ear, electronic, air conduction, broad-band noise generator and hearing aid for individuals who require both amplification and tinnitus masking.

**Literature Review:** Two clinical trials have examined the effectiveness of the Neuromonics Tinnitus Treatment. Davis et al. (2008) compared patients who received the Neuromonics Tinnitus Treatment (n=22) noise plus counseling (n=15), and counseling alone (n=13). At 12 months, the Neuromonics group was reported to have significantly better mean visual analogue scale (VAS) scores for tinnitus severity, general relaxation level, and loudness tolerance than the noise plus counseling group. Davis et al. (2007) (n=35) evaluated the relative clinical effectiveness of two variations of the Neuromonics Tinnitus Treatment system used to facilitate desensitization to the tinnitus signal. Through 12 months of follow-up, no statistically significant differences noted between treatment groups for any outcomes. Limitations for both studies include small sample size and short-term follow-up, with the lack of a control group in the latter study.

A comparative study by Folmer and Carroll (2006) assessed patients who used in-the-ear sound generators (n=50), hearing aids (n=50), or no ear-level devices (n=50), for changes in tinnitus severity. At a mean follow-up of 18 months, all three groups of patients demonstrated significant reductions in Tinnitus Severity Index scores and self-rated tinnitus loudness. There were no significant differences between the groups.

In a systematic review of 69 randomized controlled trials (RCTs) on tinnitus treatments, Dobie (1999) reported none of the treatments studied (e.g., maskers, electrical stimulation, magnetic stimulation, biofeedback, acupuncture, hypnosis, psychotherapy) had been shown to eliminate tinnitus more frequently than placebo, or to provide replicable long-term reduction in the impact of tinnitus on everyday life in excess of placebo effects.

Due to the lack of controlled clinical trials demonstrating effectiveness, there is insufficient evidence in the published, peer-reviewed literature to support the use of tinnitus masking devices and instruments.

### **Transcutaneous Electrical Nerve Stimulation (TENS)**

TENS has also been investigated as a treatment modality for tinnitus.

**Literature Review:** In a case series (n=240), Vanneste et al. (2010) applied a real and a sham TENS treatment to patients with tinnitus. Only 17.9% of the patients responded to treatment with TENS by demonstrating significant tinnitus suppression (p<0.001).

Kapkin et al. (2008) conducted an RCT of 42 patients with subjective tinnitus who received TENS (n=31), or placebo (n=11). The comparison between the average sensation level of tinnitus before and after treatment in the electrical stimulation group was not statistically significant (p=0.424). A similar comparison for the placebo group was also not statistically significant (p=0.683). The rate of improvement following the therapy was 42.8% (18/42) in the electrical therapy group and 28.5% (4/14) in the placebo group.

A systematic review (n=69 RCTs) by Dobie (1999) reported that based on the results of two RCTs, TENS was found to be ineffective for the treatment of tinnitus compared to an inactive device.

There is insufficient evidence in the published, peer-reviewed scientific literature to support TENS as a method to treat tinnitus.

### **Transmeatal Laser Irradiation**

Low-level laser applied through the external acoustic meatus of the affected ear has also been investigated as a treatment for tinnitus.

**Literature Review:** A number of prospective, randomized, double-blind studies with small patient populations (n=45–49 subjects) and short-term follow-up have evaluated the effectiveness of transmeatal laser irradiation for tinnitus (Teggi, et al. 2009; Gungor, et al., 2008; Nakashima, et al., 2002; Mirz, et al., 1999). These RCTs evaluating the effectiveness of low-level laser for tinnitus have yielded conflicting results.

Currently, there is insufficient evidence in the published, peer-reviewed scientific literature to support the use of low-level laser therapy for the treatment of tinnitus.

### **Transcranial Magnetic Stimulation (TMS)**

Repetitive TMS (rTMS) has been examined as a treatment modality for tinnitus. The technique involves the delivery of pulsed electromagnetic current across a specialized coil. When the rTMS magnetic field passes through the brain, it affects cortical nerve cells in a targeted area. It has been proposed that rTMS applied to the auditory cortex of the brain may result in the reduction of tinnitus.

**Literature Review:** There are few studies, retrospective, randomized and non-randomized, placebo-controlled trials, with small patient populations (n=14-114) in the published peer-reviewed literature evaluating the efficacy of rTMS for the treatment of tinnitus (Marcondes, et al., (2010); Rossi, et al., 2007; Kleinjung, et al., 2005; De Ridder, et al., 2005; Plewnia et al. 2003).

Additional well-designed, long-term studies with larger sample sizes are needed to define the role of rTMS in the treatment of tinnitus.

### **Cognitive Behavioral Therapy**

Cognitive behavioral therapy is a structured, time-limited psychological therapy. This treatment modality involves the use of relaxation, cognitive restructuring of thoughts and exposure to exacerbating situations in order to promote habituation. Cognitive behavioral therapy has been proposed as a treatment for tinnitus.

**Literature Review:** An updated Cochrane review (n=8 RCTs; 468 subjects) by Martinez-Devesa et al. (2010) evaluated the effectiveness of cognitive behavioral therapy on the management of tinnitus. For the primary outcome of subjective tinnitus loudness evaluated in seven trials, no significant differences were found between CBT and no treatment or another intervention.

An RCT and two waitlist-controlled trials (Kaldo, et al., 2008; Robinson, et al., 2008; Sadlier, et al., 2008) with patient populations of 25-65 and follow-up of 4-12 months have assessed the effectiveness of CBT for the treatment of tinnitus. Results of these studies suggest that treatment with CBT led to greater improvement in tinnitus distress and depression. However, the studies are limited by small sample sizes, lack of randomization and short-term follow-up.

Larger well-designed studies with longer follow-up are needed to establish the role of cognitive behavioral therapy in the management of tinnitus. There is insufficient evidence in the published peer-reviewed literature to support the use of this therapy for tinnitus treatment.

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

TRT, a treatment approach developed by Jastreboff, includes two key elements: directive counseling and sound habituation therapy using "non-masking" white-noise generators. In this context, directive counseling refers to a series of intensive, interactive, individualized educational sessions. Rather than eliminating the perceived sound of tinnitus, the aim of TRT is to habituate the patient to it (Jastreboff, 2003).

**Literature Review:** A Cochrane review (n=1 RCT; 123 subjects) by Phillips and McFerran (2010) assessed the effectiveness of TRT compared to masking for the treatment of tinnitus. The study results reported suggested that TRT was the more effective intervention. However, it was noted that the study quality was not good enough to be able to draw firm conclusions (Phillips and McFerran, 2010).

Several retrospective and prospective series with small patient populations (n=41–92) have examined the use of TRT for the treatment of tinnitus (Forti, et al., 2009; Baracca, et al., 2007; Mazurek, et al., 2006) with varying success rates reported.

Henry et al. (2006) conducted a prospective, experimental, controlled trial (n=118) to evaluate the efficacy of tinnitus masking and TRT in military veterans with clinically significant tinnitus. Patients were placed into the two groups in an alternating manner. Results indicated that both groups showed significant improvements in outcome measures, with the improvement in the TRT group being significantly greater than for the group that utilized tinnitus masking. The study is limited by the lack of a control group. In addition, the external validity of this study is decreased because the study population was limited to veterans.

Herraiz and colleagues (2005) conducted a prospective, nonrandomized clinical study (n = 158) to assess the efficacy of TRT for tinnitus relief. This three-armed study compared patients who received TRT (n=116) to a waiting list group (n=21) and a partially treated group (i.e., patients who refused prosthesis adaptation) (n=21). At 12-month follow-up, Results indicated that TRT patients showed greater improvement of their tinnitus, THI and VAS scores when compared to the waiting list group and with patients who refused prosthesis adaptation when recommended (p<0.05).

Although the success rate of TRT has been reported in literature to be as high as 80% these rates have not been proven through RCTs comparing TRT with placebo. Treatment protocols and principles of TRT have been well-defined, however, its effectiveness has not been sufficiently demonstrated through well-designed clinical trials.

### **Hearing Aids**

Standard hearing aids have been used in the treatment of tinnitus, especially when the condition is accompanied by hearing loss. It has been suggested that, for certain patients, hearing aids can provide enough sound stimulation to produce some relief from the loudness level of the tinnitus. Proponents of this theory contend that even patients with minimal hearing loss or with normal hearing may obtain a masking benefit from hearing aids through the additional auditory stimulation associated with hearing aid use. The role of standard hearing aids in the alleviation of the symptom of tinnitus has not been established. No well-designed studies have demonstrated the long-term efficacy of hearing aids for the treatment of tinnitus.

## Cochlear Implants

Similarly, some patients who received cochlear implants for profound hearing loss and who also have tinnitus have reported tinnitus relief following implantation. Nonetheless, no evidence in the published, peer-reviewed literature supports the use of cochlear implants as a treatment for patients with tinnitus who do not also have a profound or severe sensorineural deafness/hearing loss that warrants cochlear implantation.

## Hyperbaric Oxygen Therapy (HBO or HBOT)

HBO has been proposed as a treatment for tinnitus that often accompanies sensorineural hearing loss. HBOT is a mode of treatment in which a patient breathes 100% oxygen at pressures greater than normal atmospheric (i.e., sea level) pressure. HBO has been investigated as a treatment to increase the supply of oxygen to the ear and brain in an attempt to decrease the severity of hearing loss and tinnitus.

A Cochrane review by Bennett et al. (2007) evaluated the available evidence on HBOT for the treatment of tinnitus and Idiopathic sudden sensorineural hearing loss. The review included six comparative trials with a total of 308 subjects. It was concluded that the effect of HBOT on tinnitus by pooled data analysis could not be assessed. For additional information, refer to the CIGNA Hyperbaric Oxygen Therapy, Systemic & Topical Coverage Policy.

There is insufficient evidence in the published, peer-reviewed literature to support the use of HBOT for tinnitus.

## Professional Societies/Organizations

According to the American Academy of Audiology (AAA), prior to recommending or beginning any treatment for tinnitus, it is essential that a differential diagnosis be attempted. There are many factors that can cause and affect tinnitus and its perception that will influence the management plan and outcome. The treatment of patients with tinnitus is most likely to succeed when a multidisciplinary approach is used. The AAA states that although there is no cure for most cases of tinnitus, a number of treatment approaches have been described with various degrees of reported success (e.g., TRT, counseling, stress management, self-help and support groups) (AAA, 2000).

## Summary

There is insufficient evidence in the published, peer-reviewed scientific literature to support the use of any type of masking device in the treatment of tinnitus. Standardized treatment protocols and outcome measures, as well as patient selection criteria, have yet to be established. Well-designed, randomized, controlled clinical trials are lacking, and the available studies have failed to consistently demonstrate a treatment effect in excess of placebo. Likewise, due to the lack of evidence, the role of transcutaneous electrical nerve stimulation (TENS), transmeatal laser irradiation, repetitive transcranial magnetic stimulation (rTMS), cognitive behavioral therapy (CBT) and tinnitus retraining therapy (TRT), hearing aids, cochlear device implantation, and hyperbaric oxygen therapy as treatment modalities for tinnitus has not been proven.

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## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Experimental/Investigational/Unproven/Not covered when used to report these services for the management of tinnitus:**

CPT* Codes	Description
69930	Cochlear device implantation, with or without mastoidectomy
92630	Auditory rehabilitation; prelingual hearing loss
92633	Auditory rehabilitation; postlingual hearing loss
92700	Unlisted otorhinolaryngological service or procedure
96125	Standardized cognitive performance testing (eg, Ross Information Processing Assessment) per hour of a qualified health care professional's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report

99183	Physician attendance and supervision of hyperbaric oxygen therapy, per session
0161T	Therapeutic repetitive transcranial magnetic stimulation treatment delivery and management, per session
	All other codes

<b>HCPCS Codes</b>	<b>Description</b>
C1300	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval
E0720	Transcutaneous electrical nerve stimulation (TENS) device, 2 lead, localized stimulation
E0730	Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation
L8614	Cochlear device, includes all internal and external components
V5030	Hearing aid, monaural, body worn, air conduction
V5040	Hearing aid, monaural, body worn, bone conduction
V5050	Hearing aid, monaural, in the ear
V5060	Hearing aid, monaural, behind the ear
V5070	Glasses, air conduction
V5080	Glasses, bone conduction
V5100	Hearing aid, bilateral, body worn
V5120	Binaural, body
V5130	Binaural, in the ear
V5140	Binaural, behind the ear
V5150	Binaural, glasses
V5170	Hearing aid, CROS, in the ear
V5180	Hearing aid, CROS, behind the ear
V5190	Hearing aid, CROS, glasses
V5210	Hearing aid, BICROS, in the ear
V5220	Hearing aid, BICROS, behind the ear
V5230	Hearing aid, BICROS, glasses
V5242	Hearing aid, analog, monaural, CIC (completely in the ear canal)
V5243	Hearing aid, analog, monaural, ITC (in the canal)
V5244	Hearing aid, digitally programmable analog, monaural, CIC
V5245	Hearing aid, digitally programmable, analog, monaural, ITC
V5246	Hearing aid, digitally programmable analog, monaural, ITE (in the ear)
V5247	Hearing aid, digitally programmable analog, monaural, BTE (behind the ear)
V5248	Hearing aid, analog, binaural, CIC
V5249	Hearing aid, analog, binaural, ITC
V5250	Hearing aid, digitally programmable analog, binaural, CIC
V5251	Hearing aid, digitally programmable analog, binaural, ITC
V5252	Hearing aid, digitally programmable, binaural, ITE
V5253	Hearing aid, digitally programmable, binaural, BTE
V5254	Hearing aid, digital, monaural, CIC
V5255	Hearing aid, digital, monaural, ITC
V5256	Hearing aid, digital, monaural, ITE
V5257	Hearing aid, digital, monaural, BTE
V5258	Hearing aid, digital, binaural, CIC
V5259	Hearing aid, digital, binaural, ITC
V5260	Hearing aid, digital, binaural, ITE
V5261	Hearing aid, digital, binaural, BTE
V5262	Hearing aid, disposable, any type, monaural
V5263	Hearing aid, disposable, any type, binaural
V5274	Assistive listening device, not otherwise specified
V5298	Hearing aid, not otherwise classified
	All other codes

ICD-9-CM Diagnosis Codes	Description
388.30 - 388.32	Tinnitus

\*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	11/15/2007	0220	Tinnitus Instruments, Devices and Retraining Therapy

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