

Protocol

Treatment of Tinnitus

(80139)

Medical Benefit		Effective Date: 10/01/18	Next Review Date: 05/19
Preauthorization	No	Review Dates: 09/09, 09/10, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 05/17, 05/18	

This protocol considers some listed therapies investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With persistent, bothersome tinnitus	Interventions of interest are: • Psychological coping therapy	Comparators of interest are: • Standard therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With tinnitus	Interventions of interest are: • Sound therapy	Comparators of interest are: • Standard therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With tinnitus	Interventions of interest are: • Combined psychological and sound therapy	Comparators of interest are: • Standard therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With tinnitus	Interventions of interest are: • Repetitive transcranial magnetic stimulation	Comparators of interest are: • Standard therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With tinnitus	Interventions of interest are: • Electrical or electromagnetic stimulation	Comparators of interest are: • Standard therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With tinnitus	Interventions of interest are: • Transmeatal laser irradiation	Comparators of interest are: • Standard therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

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.

SUMMARY OF EVIDENCE

For individuals who have persistent, bothersome tinnitus who receive psychological coping therapy, the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. These therapies are intended to reduce tinnitus impairment and improve health-related quality of life. Meta-analyses of a variety of cognitive 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 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.

For individuals who have tinnitus who receive transmeatal laser irradiation, the evidence includes RCTs and crossover trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence for transmeatal laser irradiation includes a number of double-blind RCTs, most of which showed no treatment efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

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**:

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

NOTE: This protocol does not address surgical (e.g., cochlear or brainstem implants) or pharmacologic (e.g., use of amitriptyline or other tricyclic antidepressants) treatments of tinnitus, or injection of botulinum toxin.

Refer to Drug Therapy Guidelines for botulinum toxin A injections.

BACKGROUND

TINNITUS

Tinnitus describes the perception of any sound in the ear in the absence of an external stimulus and presents as a malfunction in the processing of auditory signals. A hearing impairment, often noise-induced or related to aging, is commonly associated with tinnitus. Clinically, tinnitus is subdivided into subjective and objective types. The latter describes the minority of cases, in which an external stimulus is potentially heard by an observer (e.g., by placing a stethoscope over the patient's external ear). Common causes of objective tinnitus include middle ear and skull-based tumors, vascular abnormalities, and metabolic derangements. The more common type is subjective tinnitus, which is frequently self-limited. In a small subset of patients with subjective tinnitus, its

intensity and persistence leads to disruption of daily life. While many patients habituate to tinnitus, others may seek medical care if the tinnitus becomes too disruptive.

Treatment

Many treatments are supportive because, currently, there is no cure. One treatment, called tinnitus masking therapy, has focused on the use of devices worn in the ear that produce a broad band of continuous external noise that drowns out or masks the tinnitus. Psychological therapies may also be provided to improve coping skills, typically requiring four to six one-hour visits over an 18-month period. Tinnitus retraining therapy, also referred to as tinnitus habituation therapy, is based on the theories of Jastreboff, who proposed that tinnitus itself is related to the normal background electrical activity in auditory nerve cells, but the key factor in some patients' unpleasant response to the noise is due to a spreading of the signal and an abnormal conditioned reflex in the extra-auditory limbic and autonomic nervous systems. The goal of tinnitus retraining therapy is to habituate (retrain) the subcortical and cortical response to the auditory neural activity. In contrast to tinnitus masking, the auditory stimulus is not intended to drown out or mask the tinnitus but is set at a level such that the tinnitus can still be detected. This strategy is thought to enhance extinction of the subconsciously conditioned reflexes connecting the auditory system with the limbic and autonomic nervous systems by increasing neuronal activity within the auditory system. Treatment may also include the use of hearing aids to increase external auditory stimulation. The Heidelberg model uses an intensive program of active and receptive music therapy, relaxation with habituation to the tinnitus sound, and stress mapping with a therapist.

Sound therapy is a treatment approach based on evidence of auditory cortex reorganization (cortical remapping) with tinnitus, hearing loss, and sound/frequency training. One type of sound therapy uses an ear-worn device (Neuromonics Tinnitus Treatment) prerecorded with selected relaxation audio and other sounds spectrally adapted to the individual patient's hearing thresholds. This is achieved by boosting the amplitude of those frequencies at which an audiogram has shown the patient to have a reduced hearing threshold. Also being evaluated is auditory tone discrimination training at or around the tinnitus frequency. Another type of sound therapy being investigated uses music with the frequency of the tinnitus removed (notched music) to promote reorganization of sound processing in the auditory cortex. One theory behind the notched music is that tinnitus is triggered by injury to inner ear hair cell population, resulting in both a loss of excitatory stimulation of the represented auditory cortex and loss of inhibition on the adjoining frequency areas. It is proposed that this loss of inhibition leads to hyperactivity and overrepresentation at the edge of the damaged frequency areas and that removing the frequencies overrepresented at the audiometric edge will result in the reorganization of the brain.

Electrical stimulation to the external ear has also been investigated and is based on the observation that electrical stimulation of the cochlea associated with a cochlear implant may be associated with a reduction in tinnitus. Transcranial magnetic stimulation, electrical stimulation, and transmeatal low-power laser irradiation have also been evaluated.

REGULATORY STATUS

The Neuromonics® Tinnitus Treatment is one of many tinnitus maskers cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. It is "...intended to provide relief from the disturbance of tinnitus while using the system, and with regular use (over several months) may provide relief to the patient whilst not using the system." FDA product code: KLW.

RELATED PROTOCOLS

Biofeedback for Miscellaneous Indications

Cochlear Implant

Low-Level Laser Therapy

Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Pichora-Fuller MK, Santaguida P, Hammill A, et al. Evaluation and Treatment of Tinnitus: Comparative Effectiveness (Comparative Effectiveness Review No. 122). Rockville, MD: Agency for Healthcare Research and Quality; 2013.
2. Martinez-Devesa P, Perera R, Theodoulou M, et al. Cognitive behavioural therapy for tinnitus. *Cochrane Database Syst Rev*. Sep 8 2010(9):CD005233. PMID 20824844
3. Zenner HP, Vonthein R, Zenner B, et al. Standardized tinnitus-specific individual cognitive-behavioral therapy: a controlled outcome study with 286 tinnitus patients. *Hear Res*. Apr 2013;298:117-125. PMID 23287811
4. Westin VZ, Schulin M, Hesser H, et al. Acceptance and commitment therapy versus tinnitus retraining therapy in the treatment of tinnitus: a randomised controlled trial. *Behav Res Ther*. Nov 2011;49(11):737-747. PMID 21864830
5. Kaldo V, Cars S, Rahnert M, et al. Use of a self-help book with weekly therapist contact to reduce tinnitus distress: a randomized controlled trial. *J Psychosom Res*. Aug 2007;63(2):195-202. PMID 17662757
6. Kaldo V, Levin S, Widarsson J, et al. Internet versus group cognitive-behavioral treatment of distress associated with tinnitus: a randomized controlled trial. *Behav Ther*. Dec 2008;39(4):348-359. PMID 19027431
7. Hesser H, Gustafsson T, Lunden C, et al. A randomized controlled trial of Internet-delivered cognitive behavior therapy and acceptance and commitment therapy in the treatment of tinnitus. *J Consult Clin Psychol*. Aug 2012;80(4):649-661. PMID 22250855
8. Jasper K, Weise C, Conrad I, et al. Internet-based guided self-help versus group cognitive behavioral therapy for chronic tinnitus: a randomized controlled trial. *Psychother Psychosom*. Jun 2014;83(4):234-246. PMID 24970708
9. Weise C, Kleinstauber M, Andersson G. Internet-delivered cognitive-behavior therapy for tinnitus: a randomized controlled trial. *Psychosom Med*. May 2016;78(4):501-510. PMID 26867083
10. Beukes EW, Baguley DM, Allen PM, et al. Audiologist-guided internet-based cognitive behavior therapy for adults with tinnitus in the United Kingdom: a randomized controlled trial. *Ear Hear*. Nov 1 2017. PMID 29095725
11. Henry JA, McMillan G, Dann S, et al. Tinnitus management: randomized controlled trial comparing extended-wear hearing aids, conventional hearing aids, and combination instruments. *J Am Acad Audiol*. Jun 2017; 28(6):546-561. PMID 28590898

12. Hobson J, Chisholm E, El Refaie A. Sound therapy (masking) in the management of tinnitus in adults. *Cochrane Database Syst Rev*. Dec 8 2010(12):CD006371. PMID 21154366
13. Hobson J, Chisholm E, El Refaie A. Sound therapy (masking) in the management of tinnitus in adults. *Cochrane Database Syst Rev*. Nov 14 2012;11:CD006371. PMID 23152235
14. Jalilvand H, Pourbakht A, Haghani H. Hearing aid or tinnitus masker: which one is the best treatment for blast-induced tinnitus? The results of a long-term study on 974 patients. *Audiol Neurootol*. May 2015; 20(3):195-201. PMID 25924663
15. Davis PB, Wilde RA, Steed LG, et al. Treatment of tinnitus with a customized acoustic neural stimulus: a controlled clinical study. *Ear Nose Throat J*. Jun 2008;87(6):330-339. PMID 18561116
16. Hanley PJ, Davis PB, Paki B, et al. Treatment of tinnitus with a customized, dynamic acoustic neural stimulus: clinical outcomes in general private practice. *Ann Otol Rhinol Laryngol*. Nov 2008;117(11):791-799. PMID 19102123
17. Herraiz C, Diges I, Cobo P, et al. Auditory discrimination training for tinnitus treatment: the effect of different paradigms. *Eur Arch Otorhinolaryngol*. Jul 2010;267(7):1067-1074. PMID 20044759
18. Okamoto H, Stracke H, Stoll W, et al. Listening to tailor-made notched music reduces tinnitus loudness and tinnitus-related auditory cortex activity. *Proc Natl Acad Sci U S A*. Jan 19 2010;107(3):1207-1210. PMID 20080545
19. Stein A, Wunderlich R, Lau P, et al. Clinical trial on tonal tinnitus with tailor-made notched music training. *BMC Neurol*. Mar 17 2016;16:38. PMID 26987755
20. Li SA, Bao L, Chrostowski M. Investigating the effects of a personalized, spectrally altered music-based sound therapy on treating tinnitus: a blinded, randomized controlled trial. *Audiol Neurootol*. Nov 12 2016;21(5): 296-304. PMID 27838685
21. Hoare DJ, Kowalkowski VL, Kang S, et al. Systematic review and meta-analyses of randomized controlled trials examining tinnitus management. *Laryngoscope*. Jul 2011;121(7):1555-1564. PMID 21671234
22. Bauer CA, Brozoski TJ. Effect of tinnitus retraining therapy on the loudness and annoyance of tinnitus: a controlled trial. *Ear Hear*. Mar-Apr 2011;32(2):145-155. PMID 20890204
23. Henry JA, Schechter MA, Zaugg TL, et al. Clinical trial to compare tinnitus masking and tinnitus retraining therapy. *Acta Otolaryngol Suppl*. Dec 2006(556):64-69. PMID 17114146
24. Phillips JS, McFerran D. Tinnitus Retraining Therapy (TRT) for tinnitus. *Cochrane Database Syst Rev*. Mar 17 2010;3(3):CD007330. PMID 20238353
25. Grewal R, Spielmann PM, Jones SE, et al. Clinical efficacy of tinnitus retraining therapy and cognitive behavioural therapy in the treatment of subjective tinnitus: a systematic review. *J Laryngol Otol*. Dec 2014; 128(12):1028-1033. PMID 25417546
26. Argstatter H, Grapp M, Hutter E, et al. The effectiveness of neuro-music therapy according to the Heidelberg model compared to a single session of educational counseling as treatment for tinnitus: a controlled trial. *J Psychosom Res*. Mar 2015;78(3):285-292. PMID 25224125
27. Cima RF, Maes IH, Joore MA, et al. Specialised treatment based on cognitive behaviour therapy versus usual care for tinnitus: a randomised controlled trial. *Lancet*. May 26 2012;379(9830):1951-1959. PMID 22633033
28. Soleimani R, Jalali MM, Hasandokht T. Therapeutic impact of repetitive transcranial magnetic stimulation (rTMS) on tinnitus: a systematic review and meta-analysis. *Eur Arch Otorhinolaryngol*. Jul 2016;273(7):1663-1675. PMID 25968009
29. Langguth B, Landgrebe M, Frank E, et al. Efficacy of different protocols of transcranial magnetic stimulation for the treatment of tinnitus: Pooled analysis of two randomized controlled studies. *World J Biol Psychiatry*. May 2014;15(4):276-285. PMID 22909265
30. Folmer RL, Theodoroff SM, Casiana L, et al. Repetitive transcranial magnetic stimulation treatment for chronic tinnitus: a randomized clinical trial. *JAMA Otolaryngol Head Neck Surg*. Aug 2015;141(8):716-722. PMID 26181507
31. Song JJ, Vanneste S, Van de Heyning P, et al. Transcranial direct current stimulation in tinnitus patients: a systemic review and meta-analysis. *ScientificWorldJournal*. Nov 2012;2012:427941. PMID 23133339

32. Pal N, Maire R, Stephan MA, et al. Transcranial direct current stimulation for the treatment of chronic tinnitus: a randomized controlled study. *Brain Stimul.* Nov-Dec 2015;8(6):1101-1107. PMID 26198363
33. Wang TC, Tyler RS, Chang TY, et al. Effect of transcranial direct current stimulation in patients with tinnitus: a meta-analysis and systematic review. *Ann Otol Rhinol Laryngol.* Feb 2018;127(2):79-88. PMID 29192507
34. Dobie RA, Hoberg KE, Rees TS. Electrical tinnitus suppression: a double-blind crossover study. *Otolaryngol Head Neck Surg.* Oct 1986;95(3 Pt 1):319-323. PMID 3108780
35. Thedinger BS, Karlsen E, Schack SH. Treatment of tinnitus with electrical stimulation: an evaluation of the Audimax Theraband. *Laryngoscope.* Jan 1987;97(1):33-37. PMID 3491942
36. Mielczarek M, Olszewski J. Direct current stimulation of the ear in tinnitus treatment: a double-blind placebo-controlled study. *Eur Arch Otorhinolaryngol.* Jun 2014;271(6):1815-1822. PMID 24337877
37. Ghossaini SN, Spitzer JB, Mackins CC, et al. High-frequency pulsed electromagnetic energy in tinnitus treatment. *Laryngoscope.* Mar 2004;114(3):495-500. PMID 15091224
38. Nakashima T, Ueda H, Misawa H, et al. Transmeatal low-power laser irradiation for tinnitus. *Otol Neurotol.* May 2002;23(3):296-300. PMID 11981384
39. Teggi R, Bellini C, Piccioni LO, et al. Transmeatal low-level laser therapy for chronic tinnitus with cochlear dysfunction. *Audiol Neurootol.* Oct 2009;14(2):115-120. PMID 18843180
40. Ngao CF, Tan TS, Narayanan P, et al. The effectiveness of transmeatal low-power laser stimulation in treating tinnitus. *Eur Arch Otorhinolaryngol.* May 2014;271(5):975-980. PMID 23605244
41. Dehkordi MA, Einolghozati S, Ghasemi SM, et al. Effect of low-level laser therapy in the treatment of cochlear tinnitus: a double-blind, placebo-controlled study. *Ear Nose Throat J.* Jan 2015;94(1):32-36. PMID 25606834
42. Lefaucheur JP, Antal A, Ayache SS, et al. Evidence-based guidelines on the therapeutic use of transcranial direct current stimulation (tDCS). *Clin Neurophysiol.* Jan 2017;128(1):56-92. PMID 27866120
43. Tunkel DE, Bauer CA, Sun GH, et al. Clinical practice guideline: tinnitus. *Otolaryngol Head Neck Surg.* Oct 2014;151(2 Suppl):S1-S40. PMID 25273878
44. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Tinnitus Masking - RETIRED (50.6). 2014; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=85&ncdver=2&bc=AAAAGAAAAAAA%3d%3d&>. Accessed January 25, 2018.