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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.

RELATED PROTOCOLS

Biofeedback for Miscellaneous Indications

Cochlear Implant

Low Level Laser Therapy

| 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 |

| Populations | Interventions | Comparators | Outcomes |
|---------------------------------|---|--|---|
| 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 (CBTs) 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 CBT or acceptance and commitment therapy (ACT) may also improve coping skills. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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-blind and adequately powered, found no benefit of notched music on the primary outcome measures of tinnitus perception and tinnitus distress, although the sub-component score of tinnitus loudness was reported to be reduced. Two more recent RCTs evaluating notched music therapy for tinnitus found no significant differences in efficacy between this approach and ordinary music therapy or counseling. 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 that the technology results in an improvement in the health outcome.

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 (Tinnitus Handicap Inventory or Tinnitus Questionnaire scores) when tinnitus retraining therapy is compared with active or sham

controls. For Heidelberg neuro-music 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 that the technology results in an improvement in the health outcome.

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 that the technology results in an improvement in the health outcome.

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 (tDCS). Moreover, while a 2017 meta-analysis found some benefit for tDCS, it was noted that further study would be needed to evaluate tDCS 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 that the technology results in an improvement in the health outcome.

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 that the technology results in an improvement in the health outcome.

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

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 4 to 6 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 (re-train) 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 the 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 re-mapping) 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 the reorganization of sound processing in the auditory cortex. One theory behind the notched music is that tinnitus is triggered by injury to the 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.

Table 1. Devices Cleared by the U.S. Food and Drug Administration

| Devices | Manufacturer | Date Cleared | 510(k) No. | Indication |
|--|--|--------------|------------|-----------------|
| Multiflex Tinnitus Technology | Starkey Laboratories | 6/19/2020 | K201370 | Tinnitus Relief |
| Tinnitus Sound Generator Module | Gn Hearing A/S | 2/20/2020 | K193303 | Tinnitus Relief |
| Tinnitus Sound Generator Module | Gn Hearing A/S | 11/30/2018 | K180495 | Tinnitus Relief |
| Audifon Tinnitus-Module | Audiofon Usa Inc. | 10/19/2017 | K171243 | Tinnitus Relief |
| Tinnilogic Mobile Tinnitus Management De | Jiangsu Betterlife Medical Co., Ltd. | 5/17/2017 | K163094 | Tinnitus Relief |
| Sound Options Tinnitus Treatment | Sound Options Tinnitus Treatments Inc. | 9/28/2016 | K161562 | Tinnitus Relief |
| Hypersound Tinnitus Module | Turtle Beach Corporation | 8/23/2016 | K161331 | Tinnitus Relief |
| Desyncra For Tinnitus Therapy System, De | Neurotherapies Reset Gmbh. | 1/20/2016 | K151558 | Tinnitus Relief |
| Reve134 | Kw Ear Lab, Inc | 10/9/2015 | K151719 | Tinnitus Relief |
| Serenity | Sanuthera, Inc. | 7/27/2015 | K150014 | Tinnitus Relief |
| Soundcure Serenade Tinnitus Treatment Sy | Soundcure, Inc. | 4/13/2015 | K150065 | Tinnitus Relief |
| Levo Tinnitus Masking Software Device | Otoharmonics Corp | 7/18/2014 | K140845 | Tinnitus Relief |
| Solace Sound Generators | Amplisound Hearing Products & Services | 3/25/2014 | K132965 | Tinnitus Relief |
| Tinnitus Sound support | Oticon A/S | 3/18/2014 | K133308 | Tinnitus Relief |
| Wave 2g, Soul | Hansaton Akustik Gmbh | 1/3/2014 | K130937 | Tinnitus Relief |

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

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