This Protocol considers this test or procedure 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.

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Description

Various nonpharmacologic treatments are being evaluated to improve the subjective symptoms of tinnitus. These approaches include cognitive and behavioral therapies coping therapies, use of tinnitus maskers, tinnitus retraining therapy, customized sound therapy, transcranial magnetic stimulation, transcranial direct current stimulation, electrical stimulation of the ear, transmeatal laser irradiation, electromagnetic energy, and botulinum toxin type A injections.

Summary of Evidence

The evidence for cognitive and behavioral coping therapies in individuals who have tinnitus includes a number of randomized controlled trials (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. One large, well-conducted RCT using an intensive, multidisciplinary intervention showed improvement in outcomes, but generalizability is a concern because it is uncertain whether the intensive treatment approach used could be replicated outside the investigational setting. Another RCT reported that a self-help/Internet-based approach to cognitive and behavioral therapy or acceptance and commitment therapy may also improve coping skills. Additional studies are needed to determine the efficacy of this treatment modality and the most effective method of delivering psychological coping therapy outside of the investigational setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for sound therapies in individuals who have tinnitus 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 a number of RCTs and a systematic review of RCTs. The RCTs have medium-to-high risk of bias and do not show efficacy of masking therapy. The evidence on tinnitus retraining therapy consists of a number of small randomized or quasi-randomized controlled trials. Together, the literature does not show a consistent improvement in the primary outcome measure (Tinnitus Handicap Inventory [THI]) when tinnitus retraining therapy is compared with active or sham controls. Research on customized sound therapy appears to be at an early stage. For example, the studies described use 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. No studies from the United States were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for transcranial magnetic stimulation in individuals who have tinnitus 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.

The evidence for transcranial direct current stimulation and direct current electrical stimulation of the ear in individuals who have tinnitus includes a number of small RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Evidence includes a number of small RCTs, many of which report no benefit of these treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for transmeatal laser irradiation, electromagnetic energy, and botulinum toxin type A 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 efficacy of this treatment. The evidence on electromagnetic energy includes a small RCT that found no benefit for the treatment of tinnitus. The evidence for botulinum toxin type A includes a small
A crossover trial that showed benefit on some outcome measures. Additional study is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

Treatment of tinnitus with tinnitus coping therapy, tinnitus maskers, tinnitus retraining therapy, customized sound therapy, transcranial magnetic stimulation, transcranial direct current stimulation, transcutaneous electrical stimulation of the ear, transmeatal laser irradiation and electromagnetic energy is considered investigational.

NOTE: This Protocol does not address surgical (e.g., cochlear or brainstem implants) or pharmacologic treatment of tinnitus, e.g., the use of botulinum toxin A injections, amitriptyline or other tricyclic antidepressants. Refer to Drug Therapy Guidelines for botulinum toxin A injections.

Background

Tinnitus describes the perception of any sound in the ear in the absence of an external stimulus and presents 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.

Many treatments are supportive in nature, as currently, there is no cure. One treatment, called tinnitus masking therapy, has focused on 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 subconscious 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.

Sound therapy is a treatment approach that is 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; Neuromonics, Australia) 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 that is being investigated uses music with the frequency of the tinnitus removed (notched music) to promote reorganization of sound processing in the auditory cortex. 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.

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. Transmeatal low-power laser irradiation, electromagnetic energy, transcranial magnetic stimulation, and botulinum toxin type A injections have also been evaluated.

**Regulatory Status**

The Neuromonics® Tinnitus Treatment is one of many tinnitus maskers that has been 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.


