Preauthorization is not required but is recommended if, despite this Protocol position, the physician feels this service is medically necessary.

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.

Description

A variety of nonpharmacologic treatments are being evaluated to improve the subjective symptoms of tinnitus. These approaches include use of tinnitus maskers, electrical stimulation, transmeatal laser irradiation, electromagnetic energy, tinnitus-retraining therapy, cognitive and behavioral therapies, transcranial magnetic stimulation, transcutaneous electrical stimulation, sound therapy, and botulinum toxin A injections.

Summary of Evidence

A variety of treatments have been evaluated for the treatment of tinnitus. Cognitive and behavioral coping therapies have been reported to reduce tinnitus impairment and improve health-related quality of life. One large, well-conducted randomized controlled trial (RCT) using an intensive, multidisciplinary intervention showed improvement in outcomes, but it is uncertain whether the intensive treatment approach used could be replicated outside the investigational setting. Other RCT results suggest that a self-help/Internet-based approach to cognitive and behavioral therapy or acceptance and commitment therapy (ACT) may also improve coping skills. Additional studies are needed to determine the most effective method of delivering psychological coping therapy outside of the investigational setting. As a result, tinnitus coping therapy, such as cognitive-behavioral interventions and ACT, are considered investigational.

Current evidence is insufficient to show improved health outcomes in patients treated with tinnitus maskers, electrical stimulation, transmeatal laser irradiation, electromagnetic energy, tinnitus-retraining therapy, sound therapy, transcranial magnetic stimulation, transcutaneous electrical stimulation, or botulinum toxin A injections. Therefore, these treatments are considered investigational.

Policy

Treatment of tinnitus with tinnitus maskers, electrical stimulation, transmeatal laser irradiation, electromagnetic energy, tinnitus-retraining therapy, tinnitus coping therapy, transcranial magnetic stimulation, transcutaneous electrical stimulation, or sound therapy is considered investigational.

NOTE: This Protocol does not address 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; the latter describes the minority of cases in which an external stimulus is potentially heard by an observer, for example 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. In most cases, tinnitus is subjective and frequently self-limited. In a small subset of patients with subjective tinnitus, its 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. Jastreboff 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.

Transcutaneous 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 A injections have also been evaluated.

Regulatory Status

The Neuromonics® Tinnitus Treatment is one of many Tinnitus Maskers that has been cleared for marketing as a tinnitus masker through FDA’s 510(k) process and 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
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.


