The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.** 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 non-pharmacologic 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.

**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 the majority of 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 a researcher named Jastreboff. Jastreboff proposed that tinnitus itself is related to the normal background electrical activity in auditory nerve cells, but the key factor is the subject’s unpleasant perception of the noise, which is governed by an abnormal conditioned response in the extra-auditory limbic system. The goal of tinnitus-retraining therapy is to retrain the subcortical and cortical centers involved in processing the tinnitus signals and habituate 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 set at a level such that the tinnitus can still be detected. This strategy is thought to enhance habituation to the tinnitus by increasing the 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 utilizes music with the frequency of the tinnitus removed (notched music) to promote reorganization of sound processing in the auditory cortex.

Transcutaneous electrical stimulation to the external ear has also been investigated and is based on the observation that the 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 has been cleared for marketing as a tinnitus masker through the U.S. Food and Drug Administration’s (FDA) 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.”

**Related Protocols:**

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

Low-Level Laser Therapy

**Corporate Medical Guideline**

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.

**References**

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


38. National Coverage Determination (NCD) for Tinnitus Masking (50.6). This is a longstanding national coverage determination. The effective date of this version has not been posted.