MEDICAL POLICY

POLICY TITLE	TREATMENT OF TINNITUS
POLICY NUMBER	MP 2.038

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**6/1/2024**

I. POLICY

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 electrical stimulation of the ear
- Electromagnetic energy
- Transmeatal laser irradiation.

There is insufficient evidence to support a general conclusion concerning the health outcomes related to their efficacy for the above listed investigational indications.

Note: This policy does not address surgical (e.g., cochlear or brainstem implants); pharmacologic treatment of tinnitus (e.g., use of amitriptyline or other tricyclic antidepressants), or injection of botulinum toxin.

Cross-references:

MP 1.023 Cochlear Implant
MP 1.097 Low Level Laser Therapy
MP 2.064 Biofeedback and Neurofeedback Therapy

II. PRODUCT VARIATIONS

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MEDICAL POLICY

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies .

III. DESCRIPTION/BACKGROUND

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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 in nature because, 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 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 (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. 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; 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. One theory behind 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 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. Transmeatal low-power laser irradiation, electrical stimulation, and transcranial magnetic stimulation 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.

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have persistent, bothersome tinnitus who receive psychological coping therapy, the evidence includes 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 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-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. 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. One additional RCT found tailor-made notched music therapy and tinnitus retraining therapy both improved tinnitus handicap inventory (THI) and visual analog scale (VAS) scores from baseline to 3 months follow-up, but the notched music therapy group had significantly improved THI scores at 1-month follow-up and VAS scores at 3 months follow-up compared to tinnitus retraining therapy. 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 (Tinnitus Handicap Inventory or Tinnitus Questionnaire 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.

V. DEFINITIONS

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TINNITUS is a subjective ringing, buzzing, or hissing sound in the ear. For some patients, this causes only minor irritation; for others, it is disabling.

BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VI. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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; therefore, not covered:

Procedure Codes							
E0720	E0746	E0761	E1399	G0283	S8948	90867	90868
90869	90875	90876	90901	92507	97014	97026	97032
97039							

VIII. REFERENCES

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IX. POLICY HISTORY

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MP 2.038	**09/11/2020 Consensus review.** No change to Policy Statement. Coding reviewed, no changes. References reviewed, updated. Product Variation Statement updated. FEP statement updated.
	06/21/2021 Consensus review. No change to policy statement. Coding reviewed with no changes. References reviewed and updated. Product Variation statement updated.
	06/06/2022 Consensus review. No changes to policy statement. FEP and references updated. Coding reviewed with no changes.
	01/03/2023 Consensus review. No change to policy statement. References and background reviewed and updated.
	05/24/2023 Consensus review. No change to policy statement. Rationale and references updated. No change to coding.
	02/27/2024 Consensus review. No change to policy statement. Updated background, rationale, references. Coding reviewed, no changes.

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