Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:
Treatment of Tinnitus

Policy #: 482
Latest Review Date: February 2023
Category: Medical
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **treatment of tinnitus** as a **non-covered benefit** and as **investigational** for all indications, including but not limited to the following indications:

- Tinnitus coping therapy
- Tinnitus maskers
- Tinnitus-retraining therapy (combined psychological and sound therapy)
- Customized sound therapy
- Transcranial magnetic stimulation
- Transcranial direct current stimulation
- Electrical transcutaneous stimulation of the ear
- Transmeatal laser irradiation
- Electromagnetic energy
- Botulinum toxin Type A injections
- Biofeedback (contract exclusion)
- Cognitive-behavioral therapy
- Self-help cognitive-behavioral therapy
- Acceptance and Commitment therapy
- Ozone therapy

NOTE: This policy does not address surgical (e.g., cochlear or brainstem implants) or pharmacologic treatment of tinnitus (e.g., the use of amitriptyline or other tricyclic antidepressants).

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

Tinnitus

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 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 the 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.

KEY POINTS:

The most recent literature review was updated through January 19, 2023.

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 have found improvement 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 insufficient to determine the effects of the technology on health outcomes.

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 have medium-to-high risk of bias and did not show efficacy of masking therapy. Research on customized sound therapy appears to be at an early stage. For example, the studies described 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. 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 (e.g., tinnitus retraining 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-randomized controlled trials. Together, the literature does not show a consistent improvement in the primary outcome measure (Tinnitus Handicap Inventory) when tinnitus retraining therapy is compared with active or sham controls. For Heidelberg neuromusic therapy, one 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 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The available evidence does not currently support use of these treatments. 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 efficacy of this treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements:
American Academy of Otolaryngology-Head and Neck Surgeons
In 2014 the American Academy of Otolaryngology-Head and Neck Surgeons published evidence-based guidelines on Tinnitus. Table 1 provides some of the Academy's recommendations.

Table 1. Guidelines on Treatment of Tinnitus

Recommendation	**SOR**	GOE
"Clinicians must differentiate patients with bothersome tinnitus from patients with non bothersome tinnitus"	Strong recommendation	B
"Clinicians should distinguish patients with bothersome tinnitus of recent onset from those with persistent symptoms (≥ 6 months) to prioritize intervention and facilitate discussion about natural history and follow-up care"	Recommendation	B

"Clinicians may recommend sound therapy to patients with persistent, bothersome tinnitus"	Option	C
"Clinicians should recommend cognitive behavioral therapy to patients with persistent, bothersome tinnitus"	Recommendation	A
"Clinicians should not routinely recommend antidepressants, anticonvulsants, anxiolytics, or intratympanic medications for a primary indication of treating persistent, bothersome tinnitus"	Recommendation against	B
"Clinicians should not recommend transcranial magnetic stimulation for the routine treatment of patients with persistent, bothersome tinnitus"	Recommendation against	

GOE: grade of evidence; SOR: strength of recommendation.

U.S. Preventative Services Task Force Recommendations
Not applicable.

KEY WORDS:

Tinnitus, tinnitus maskers, electrical stimulation, transmeatal laser irradiation, electromagnetic energy, tinnitus-retraining therapy, tinnitus coping therapy, transcranial magnetic stimulation, transcutaneous electrical stimulation, sound therapy, or botulinum toxin A injections masking device, sound therapy, treatment of tinnitus, Tinnitus Sound Generator Module, Audifon Tinnitus-Module, Tinnilogic Mobile Tinnitus Management De, Sound Options Tinnitus Treatment, Hypersound Tinnitus Module, Desyncra For Tinnitus Therapy System, De

APPROVED BY GOVERNING BODIES:

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

Table 2. Devices Cleared by the US FDA

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 System	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 Soundsupport	Oticon A/S	3/18/2014	K133308	Tinnitus Relief

Wave 2g, Soul	Hansaton Akustik Gmbh	1/3/2014	K130937	Tinnitus Relief

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Coding:

90832-90838	Psychotherapy code range
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92625	Assessment of tinnitus (includes pitch, loudness matching, and masking)
96158	Health behavior intervention, individual, face to face; initial 30 minutes
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97026	Application of a modality to 1 or more areas; infrared
0552T	Low-level laser therapy, dynamic thermokinetic energies, provided by a physician or other qualified health care professional

HCPCS Coding:

E0720	Transcutaneous electrical nerve stimulation (TENS) device, two-lead, localized stimulation
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes

Tinnitus-masking devices represent a piece of durable medical equipment. There is currently no specific HCPCS code describing these devices.

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POLICY HISTORY:

Adopted for Blue Advantage, Effective December 2014
Medical Policy Group, May 2015
Medical Policy Group, March 2016
Medical Policy Group, March 2017
Medical Policy Group, March 2018
Medical Policy Group, April 2019
Medical Policy Group, December 2019: 2020 Annual Coding update
Medical Policy Group, February 2020: added CPT code 0552T.
Medical Policy Group, March 2021
Medical Policy Group, February 2022
Medical Policy Group, February 2023
Medical Policy Group, May 2023
Medical Policy Group, November 2023: Archived effective 11/1/2023.
