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Medical Policy

Subject:	Transtympanic Micropressure ~~for the Treatment of Ménière's Disease~~		
Document #:	DME.00024	**Publish Date:**	07/07/2021~~07/08/2020~~
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Description/Scope

This document addresses the ~~application~~ use of transtympanic micropressure treatment, which has been proposed for the treatment of Ménière's disease, a disorder of the inner ear characterized by ear pressure, tinnitus, fluctuating hearing loss, and episodes of dizziness.

Position Statement

Investigational and Not Medically Necessary:

Transtympanic micropressure treatment ~~applications are~~ is considered **investigational and not medically necessary** for all indications, including, but not limited to, treatment of Ménière's disease.

Rationale

The symptoms of Ménière's disease, also called idiopathic endolymphatic hydrops, are thought to be related to disturbances in the volume/pressure relationship of the endolymphatic fluid of the inner ear, in part based on documented expansion (hydrops) of the endolymphatic spaces in the temporal bones of symptomatic individuals. Transtympanic application of intermittent bursts of air under pressure to the tympanic membrane delivered with a tympanostomy tube in place has been investigated as a means of reducing endolymphatic hydrops, but the mechanism whereby this may be achieved is poorly understood. Multiple mechanisms have been proposed including that pressure changes may lead to a reduction in endolymphatic volume, hormonal changes (atrial natriuretic peptide), changes in oxygenation, or down-regulation of endolymphatic fluid production. One such pressure-applying generator approved by the U.S. Food and Drug Administration (FDA) in 1999 for the

symptomatic treatment of Ménière's disease is the Meniett® device (Pascal Medical AB, Sweden). In 2001, Medtronic Xomed, Inc, (Jacksonville, FL), purchased the device from Pascal Medical.

Boudewyns and colleagues (2005) reported on 12 individuals with drug resistant Ménière's disease treated with the Meniett device for a mean follow-up of 39 months. There was an initial decrease in the frequency of vertigo episodes in these individuals, but no improvement in functional level, self-perceived dizziness handicap, hearing status or tinnitus. After 1 year, only 2 individuals preferred to continue with the therapy. The authors concluded Meniett therapy is unlikely to be helpful in the long-term treatment of severe, drug resistant Ménière's disease.

Gates and colleagues (2004) studied 62 individuals with unilateral Ménière's disease who were randomized to receive either the Meniett device or a sham device. Although there was a significant decrease in the incidence of vertigo in the treatment group compared to controls, this difference diminished toward the 4-month study endpoint, apparently due to spontaneous improvement in the control group. There was no difference between the groups, however, with regard to hearing and electrocochleographic results. In the 2-year follow-up phase of this trial, Gates and colleagues (2006) subsequently reported on 61 of 67 participants from both the control and active treatment groups who were treated openly with the Meniett device; 3 participants were subsequently lost to follow-up or excluded due to concurrent health problems. Vertigo episodes were self-reported on a daily symptom diary (44 participants) or by a structured telephone interview (17 participants). Of the 58 participants, 15 were in remission at the time of entry and of the 43 who had active vertigo, 20 went into remission during the 2-year follow-up; 14 (24%) dropped out to seek alternative surgical treatment, 5 (9%) showed little or no improvement, and 39 (67%) reported being in remission or substantially improved. For participants who went into remission, there was an 80% probability of remaining in remission for the 2 years. This assessment is limited, however, by the lack of a control group and treatment blinding.

Thomsen and colleagues (2005) conducted an 8-week randomized multicenter, double-blind, placebo-controlled clinical trial (n=40) using the Meniett device in individuals with active Ménière's disease. The primary endpoints were change in frequency of vertigo, change of functionality profile and change in the participant's perception of vertigo as measured on a visual analogue scale. Participants were evaluated for 2 months to obtain a baseline, after which tympanostomy tubes were placed, followed by 2 months without treatment to account for the effect of the tympanostomy tubes. A total of 20 participants then received the Meniett device for therapy and the other 20 participants received a sham device that was identical to the active device but applied only a slight pressure increase to 2 centimeters water for 5 seconds. Participants were evaluated at 2, 4, and 8 weeks of use. Outcomes

demonstrated significant improvement in functional level and in the participant's perception of vertigo in those receiving therapy with the Meniett device compared to the control group. However, there was no significant reduction in frequency of vertigo in those using the Meniett device and no statistical difference between the groups for tinnitus, hearing, or aural pressure perception. In addition to the marginal improvement in efficacy over placebo, study limitations include a small number of participants, a high dropout rate (37%), lack of intent-to-treat analysis, and the inability to rule out the possibility participants were able to discern the type of device they were assigned.

Several retrospective case series (12 to 36 subjects) reporting 2- to 4-year outcomes with the Meniett device in individuals who failed medical therapy have been published in the peer-reviewed literature (Barbara, 2007; Dornhoffer and King, 2008; Huang, 2009; Mattox and Reichert, 2008; Park, 2009; Shojaku, 2011). Although these reports suggest a potential benefit of transtympanic micropressure, they are limited in drawing conclusions due to lack of randomization and treatment blinding.

Martín Gonzalez and colleagues (2010) reported on the largest case series of 252 subjects diagnosed with definitive or probable Ménière's disease. The authors found "no evidence for the most adequate medical treatment among the different alternatives described in the literature." Concerning use of the Meniett device for Ménière's disease, "long-term results (over two years) remain unknown."

Gurkov and colleagues (2012) conducted a randomized, double-blind clinical trial at a tertiary otolaryngology clinic in Germany. After ventilation tube (VT) placement, 74 individuals with unilateral ~~Menière's~~Ménière's disease, unresponsive to betahistine treatment, received active or blinded treatment with the Meniett low-pressure generator to determine the effect of the Meniett on the subjective symptoms and audiovestibular disease markers of the participants. Prior to VT tube placement, all study participants were observed for 4 weeks in order to document their symptom severity. The participants were observed for another 4 weeks after VT tube placement. Active or sham treatment was subsequently administered by the participant 3 times a day for 16 weeks, including visits to the clinic every 4 weeks to assess ongoing compliance with use of the device along with undergoing audiometry and air caloric testing. Primary outcome measures were self-reported. Participants recorded the severity of vertigo and its influence on their daily activities using a 5-point Likert scale. The investigator then calculated vertigo and activity scores, the number of vertigo days, vertigo-free days and sick days. The investigators also stated the placebo device had identical acoustic properties to the Meniett, but administered only a slight pressure increase (placebo at 2 cm H_2O; active treatment pressure pulses at 6 Hertz within the range of 0 to 20 cm H_2O), suggesting that they could not completely exclude the possibility that the slight pressure impulses of the placebo device may have had a

therapeutic effect. Of the 68 participants that completed the study, the treatment effect, was reported as significantly greater in the active treatment group (6.5 in the active treatment group versus 1.19 in the placebo group, p=0.048). The mean number of definitive vertigo days decreased in both groups, but the treatment effect was not significantly greater in the active treatment group (p=0.102). No significant differences in the treatment effect between the active and placebo treatment groups were reported in the measures of vertigo-free days, activity scores, hearing levels, and horizontal semicircular canal function. Limitations of this study include potential participant bias in the reporting of subjective symptoms and the short follow-up period of only 4 months.

Russo and colleagues (2017) reported on an industry-sponsored, multicenter, double-blind randomized controlled trial of 129 participants with ~~Menière's~~Ménière's disease not controlled by conventional medical treatment. The trial had three phases: 1) placement of a transtympanic tube and evaluation of its effect (if resolution of symptoms, the participant was withdrawn); 2) randomization to 6 weeks of Meniett device or placebo treatment; and 3) removal of the device and 6-week follow-up period. A total of 97 participants (75%) who continued to have symptoms (≥ two vertigo episodes during a 6-week period) after placement of a transtympanic tube were randomized to an active (n=49) or sham (n=48) device for 6 weeks, and followed for the additional 6 weeks. The evaluation criteria were the number of vertigo episodes (at least 20 minutes with a 12-hour free interval) and the impact on daily life as assessed by self-questionnaires. There was a significant decrease in vertigo episodes in both groups (p=0.07); however, the number of vertigo episodes during the baseline period did not differ significantly between groups (p=0.11) (placebo group, decrease from 4.3 ± 0.6 during the first phase to 2.6 ± 0.5 after 6 weeks of treatment, and to 1.8 ± 0.8 after the removal of the device; Meniett device group, decrease from 3.2 ± 0.4 episodes during the first phase, 2.5 ± after 6 weeks of Meniett device treatment, and 1.5 ± 0.2 after the third phase). Vertigo-related quality of life also did not differ between groups.

Other Considerations

Ahsan and colleagues (2015) performed a systematic review and meta-analysis of the peer-reviewed literature for studies that included individuals with a definitive diagnosis of unilateral Ménière's disease, treatment with the Meniett device, vertigo control results, and hearing results before and after treatment. The available randomized controlled trials and other types of case-control studies were assessed for outcomes such as improvements in vertigo, American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) functional score, and pure tone average (PTA). A total of 18 studies met criteria for review; 12 studies were included in the meta-analysis. Eight studies reported a significant improvement in PTA after Meniett treatment (p=0.0085). Due to heterogeneity, data could not be combined for AAO-HNS functional score. Six studies reported that Meniett treatment

significantly reduced the frequency of vertigo ($p \leq 0.0001$) in individuals with active Meniere's disease who failed conventional treatments. Limitations of this analysis include that the majority of the data evaluated was based on retrospective and level 4 cross-sectional studies; only two randomized controlled trials were included in the final statistical analysis. Other limitations include the short follow-up period (average, 5 months), low number of participants in the treatment and control groups, and lack of reporting results in standardized measurements.

In a Cochrane review, Van Sonsbeek and colleagues (2015) assessed the available randomized controlled trials that compared use of positive pressure therapy (using the Meniett or a similar device) with placebo in individuals with Ménière's disease. The primary outcome was control of vertigo; secondary outcomes were loss or gain of hearing, severity of tinnitus, perception of aural fullness, functional level, complications or adverse effects, and sick days. A total of five prospective, randomized, double-blind, placebo-controlled clinical trials with 265 participants were included in the analysis. For the primary outcome, control of vertigo, it was not possible to pool data due to heterogeneity in the measurement of the outcome measures. No significant difference was found in most studies between the positive pressure therapy group and the placebo group in vertigo scores or vertigo days; only one study with a low risk of bias showed a significant difference in one measure of vertigo control with positive pressure therapy. Pooled analysis was not performed for most secondary outcomes as there was inadequate or lack of data for a specific outcome measurement. The authors concluded there was no evidence from the evaluable studies to demonstrate that positive pressure therapy was effective for symptoms of Ménière's disease. In addition, there was some moderate quality evidence (n=2 studies) that hearing levels were worse in individuals who used positive pressure therapy for Ménière's disease.

The Equilibrium Committee of the AAO-HNS and the Board of Directors of the AAO-HNS (2016) has published a statement on the use of transtympanic micropressure for Ménière's disease:

> We find that there is some medical evidence to support the use of micropressure therapy (such as the Meniett device) in certain cases of Meniere's disease. Micropressure therapy can be used as a second level therapy when medical treatment has failed. The device represents a largely non-surgical therapy that should be available as one of the many treatments for Meniere's disease.

This statement, however, does not identify any peer-reviewed published evidence to support this recommendation.

In 2020 the AAO-HNS published a new guideline addressing the diagnosis and treatment of Ménière's disease (Basura, 2020). That document provides the following recommendation regarding the use of transtympanic micropressure therapy:

> STATEMENT 10. POSITIVE PRESSURE THERAPY: Clinicians should not prescribe positive pressure therapy to patients with Ménière's disease. Recommendation against based on a systematic review and randomized trials showing ineffectiveness of devices like the Meniett devices with a preponderance of benefit over harm for not using.

They proceed to discuss the quality and conclusions of the available evidence, and address the studies previously described above.

In summary, the evidence for positive pressure therapy for Ménière's disease consists of randomized, placebo-controlled studies, most of which have not found a significant difference between the 2 groups in the control of vertigo. In addition, some studies have suggested worse outcomes for hearing with the use of positive pressure therapy. Therefore, additional study is needed measuring long-term outcomes in order to establish the clinical utility of transtympanic micropressure therapy as a treatment for Ménière's disease.

Background/Overview

According to the National Institutes of Health (NIH), there are approximately 615,000 individuals with Ménière's disease in the United States, with 45,500 newly diagnosed cases each year. The cause of Ménière's disease is unknown, although it has been associated with abnormalities in the fluid held in the canals of the inner ear. The disease is characterized by episodes of vertigo, fluctuating hearing loss, tinnitus (ringing in the ears), and ear pressure. Symptoms are frequently limited to one side but, according to the American Academy of Family Physicians, up to 30% of sufferers have bilateral disease. The disease is neither contagious nor fatal, but it is associated with significant morbidity. There is no cure available at this time.

Individuals with Ménière's disease do not suffer from constant symptoms. The disease is characterized by occasional "attacks" which may occur as frequently as daily or as rarely as once a year. The most frequent and serious symptom is vertigo, which involves a whirling dizziness that forces the sufferer to lie down. Vertigo may lead to nausea, vomiting and sweating. Most attacks also involve tinnitus, fullness in the ears and some loss of

hearing. All these symptoms are temporary; however progressive hearing loss in the affected ear over the course of time is common. There is frequently little or no warning of an attack. Individuals who do have warning signs of an attack, report having hearing loss, ringing, or "fullness" in their ear prior to the attack. Attacks may last anywhere from 20 minutes to several hours, and are often unpredictable and incapacitating.

Therapy for Ménière's disease is symptomatic in nature and does not address the underlying cause. Although the pathophysiology of Ménière's disease is not precisely known, it is thought to be related to a disturbance in the pressure/volume relationship of the fluid within the inner ear. The current therapy for attacks is for the individual to lay supine on a non-moveable surface such as a floor, limiting food and fluid intake until the symptoms subside, and visually focusing on a single immobile object. Conservative therapy includes a low sodium diet and diuretics to reduce the fluid accumulation, and pharmacologic therapy to reduce vestibular (balance) symptoms. Individuals who do not respond to these conservative measures may receive intratympanic gentamicin as a technique to chemically ablate vestibular function on the affected side. When symptoms continue and the unpredictability and fear of attacks persist, some individuals elect for more invasive therapy, including surgical procedures such as endolymphatic sac surgery, labyrinthectomy, or vestibular neurectomy. There is currently no therapy available to restore hearing loss that may occur.

Researchers have noted symptoms of Ménière's disease improve with fluctuations in ambient pressure; some individuals with acute vertigo have been successfully treated in hyperbaric chambers. It is hypothesized the application of low-frequency, low-amplitude pressure pulses to the middle ear to evacuate endolymphatic fluids from the middle ear relieves vertigo.

In 1999, the Meniett device received Class II device approval from the FDA as a symptomatic treatment of Ménière's disease. The device consists of a hand-held air pressure generator which delivers intermittent complex pressure pulses. Use of the device consists of 2 phases: 1) a conventional VT is surgically placed in the eardrum of the ear to be treated; and, 2) individuals are instructed to place an ear-cuff in the external ear canal to minimize leakage to the external environment. Individuals are typically instructed to use the device 3 times daily for 3 to 5 minutes each application.

Definitions

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Endolymphatic fluid: Pale, transparent, potassium-rich fluid present in the labyrinth of the inner (middle) ear, separated by a membrane from sodium-rich perilymphatic fluid.

Ménière's disease: A disease of the inner ear associated with vertigo, tinnitus and deafness.

Transtympanic micropressure: A treatment for Ménière's disease involving small variations in air pressure applied to the affected ear.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

HCPCS

A4638	Replacement battery for patient-owned ear pulse generator, each
E2120	Pulse generator system for tympanic treatment of inner ear endolymphatic fluid

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

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13. Russo FY, Nguyen Y, De Seta D, et al. Meniett device in Meniere disease: randomized, double-blind, placebo-controlled multicenter trial. Laryngoscope. 2017; 127(2):470-475.
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15. Syed MI, Rutka JA, Hendry J, Browning GG. Positive pressure therapy for Ménierè's syndrome/disease with a Meniett device: a systematic review of randomized controlled trials. Clin Otolaryngol. 2015; 40(3):197-207.
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Government Agency, Medical Society, and Other Authoritative Publications:

1. American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). Micropressure therapy - Meniere's disease. Revised 2016. Available at: http://www.entnet.org/content/micropressure-therapy. Accessed on March 6, 2021~~April 17, 2020~~.
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Websites for Additional Information

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Index

Meniett Device

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action

Revised	05/13/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Title. Clarified INV and NMN statement. Updated Scope, Rationale and References sections.
Reviewed	05/14/2020	~~Medical Policy & Technology Assessment Committee (~~MPTAC~~)~~ review. References section was updated.
Reviewed	06/06/2019	MPTAC review. References section was updated.
Reviewed	07/26/2018	MPTAC review. Updated References and Websites for Additional Information sections.
	05/15/2018	The document header wording updated from "Current Effective Date" to "Publish Date."
Reviewed	08/03/2017	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections.
Reviewed	08/04/2016	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections. Removed ICD-9 codes from Coding section.
Reviewed	08/06/2015	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections.
Reviewed	08/14/2014	MPTAC review. Updated Description, Rationale, Background, References, and Websites for Additional Information sections.
Reviewed	08/08/2013	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections.
Reviewed	08/09/2012	MPTAC review. Updated Description, Rationale, References, Websites for Additional Information, and Index.
Reviewed	08/18/2011	MPTAC review. Updated Rationale, References and Websites for Additional Information.
Reviewed	08/19/2010	MPTAC review. Updated Rationale and References.
Reviewed	08/27/2009	MPTAC review. Updated Description, Rationale and References.
Reviewed	08/28/2008	MPTAC review. Revised title, deleting (including Meniett® Device). Updated Rationale, Discussion, and References.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	08/23/2007	MPTAC review. Updated Rationale and References.

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Reviewed	09/14/2006	MPTAC review. Updated References.
Reviewed	06/08/2006	MPTAC review. Updated References.
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organization	Last Review Date	Document Number	Title
Anthem, Inc.	04/28/2005	DME.00024	Transtympanic Micropressure for the Treatment of Ménière's Disease (including Meniett™ device)
WellPoint Health Networks, Inc.	04/28/2005	2.03.14	Transtympanic Micropressure Application as a Treatment of Meniere's Disease

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