

## Medical Policy



### Title: **Transtympanic Micropressure Applications as a Treatment of Meniere's Disease**

**Professional**

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Populations	Interventions	Comparators	Outcomes
Individuals: • With Meniere disease	Interventions of interest are: • Transtympanic micropressure therapy (Meniett)	Comparators of interest are: • Medical management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

**DESCRIPTION**

Meniere disease is an idiopathic disorder of the inner ear characterized by episodes of vertigo, fluctuating hearing loss, tinnitus, and ear pressure. Conservative therapy includes a low sodium diet and diuretics to reduce fluid accumulation (ie, hydrops) and pharmacologic therapy to reduce vestibular symptoms. Transtympanic pressure treatment has been proposed as an alternative treatment for Meniere disease. This

treatment involves use of a handheld device (eg, Meniett) that delivers air pressure pulses to the ear.

## **Background**

### **Objective**

The objective of this evidence review is to determine whether transtympanic micropressure therapy improves the net health outcome in individuals who have Meniere disease.

### **Meniere Disease**

Meniere disease is an idiopathic disorder of the inner ear characterized by episodes of vertigo, fluctuating hearing loss, tinnitus, and ear pressure. The vertigo attacks are often unpredictable, incapacitating and may prevent activities of daily living. Therapy addresses symptoms, not the underlying pathophysiology. Although the pathophysiology of Meniere disease is not precisely known, it is thought to be related to a disturbance in the pressure-volume relationship of the endolymph within the inner ear.

### **Treatment**

Conservative therapy includes a low sodium diet and diuretics to reduce fluid accumulation (ie, hydrops) and pharmacologic therapy to reduce vestibular symptoms. Persons who do not respond to these conservative measures may receive gentamicin drops in the ear, as a technique of chemical labyrinthectomy to ablate vestibular function on the affected side. No therapy is available to restore hearing loss.

There has been interest in developing a more physiologic treatment approach by applying local transtympanic pressure to restore the underlying fluid homeostasis. Researchers have noted that symptoms of Meniere disease improve with fluctuations in ambient pressure, and patients with acute vertigo have been successfully treated in hypobaric chambers. It is hypothesized that the application of low-frequency, low-amplitude pressure pulse to the middle ear functions to evacuate endolymphatic fluids from the inner ear, thus relieving vertigo.

Transtympanic micropressure treatment for Meniere disease involves use of a handheld air pressure generator (Meniett) that delivers intermittent complex pressure pulses. For this device to be used, a conventional ventilation tube is surgically placed in the eardrum. Patients then place an ear-cuff in the external ear canal and treat themselves for three minutes, three times daily. Treatment continues for as long as patients have vertigo attacks.

### **Regulatory Status**

In 1999, the Meniett® device (Medtronic Xomed, Jacksonville, FL) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process specifically as a symptomatic treatment of Meniere's disease.

## **POLICY**

Transtympanic micropressure applications as a treatment of Meniere disease are considered **experimental / investigational**.

### Policy Guidelines

Use of the Meniett device requires a prior tympanostomy procedure, a novel indication for this common procedure.

## **RATIONALE**

This evidence review has been updated with searches of the MEDLINE database. The most recent literature update was performed through December 6, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Meniere disease has a variable natural history, with waxing and waning symptomatology and spontaneous recovery. Also, some outcome measures are subjective and, thus, may be particularly susceptible to placebo effects. For of these reasons, controlled trials are essential to demonstrate the clinical effectiveness of treatment of transtympanic micropressure therapy compared with alternatives (eg, continued medical management).

### **Transtympanic Micropressure Therapy for Meniere Disease Clinical Context and Therapy Purpose**

The purpose of transtympanic micropressure therapy is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medical management, in patients with Meniere disease.

The question addressed in this evidence review is: does transtympanic micropressure therapy improve the net health outcome for individuals with Meniere disease?

The following PICOTS were used to select literature to inform this review.

### **Patients**

The relevant population of interest are individuals with Meniere disease.

### **Interventions**

The therapy being considered is transtympanic micropressure therapy.

### **Comparators**

The main comparator of interest is medical management.

### **Outcomes**

The outcomes of interest are symptoms, functional outcomes, QOL, and treatment-related morbidity.

### **Timing**

Time for follow-up ranges from months to years for outcomes of interest.

### **Setting**

Patients are actively managed by otolaryngologists in an outpatient clinical setting.

### **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- d. Studies with duplicative or overlapping populations were excluded.

The data submitted to the U.S. Food and Drug Administration as part of the Food and Drug

Administration approval process of the Meniett device consisted of a case series of 20 patients.<sup>1</sup> Other case series have been published in the peer-reviewed literature, some reporting 2- to 4-year outcomes in patients who had failed conservative medical therapy.<sup>2,3,4,5,6,7,8</sup> These case series do not provide significant information about the comparative effectiveness of the Meniett device due to the lack of control groups, and they will not be discussed further in this review. The remaining literature review focuses on systematic reviews and RCTs.

### **Systematic Reviews**

A 2015 Cochrane review on positive pressure therapy for Meniere disease included 5 double-blind, placebo-controlled randomized trials (total n=265 patients).<sup>9</sup> Three trials were considered to be at low-risk of bias, one was at unclear risk, and one was at high-risk. Results on the primary outcome measure (control of vertigo) could not be pooled due to heterogeneity in measurement, but most trials showed no significant difference in vertigo between Meniett therapy and placebo. Reviewers concluded that evidence did not support the effectiveness of positive pressure therapy for the treatment of Meniere disease and there was some evidence that

hearing is impaired with this treatment. Another systematic review (2015), which included four of the same RCTs that specifically used the Meniett device, also found no significant difference between low-pressure therapy and placebo for the frequency of vertigo.<sup>10</sup>

### **Randomized Controlled Trials**

The three trials, considered to be of low-risk of bias in the Cochrane review, are described next. Gates et al (2004) reported on the 4-month results of a randomized, multi-institutional trial that enrolled 67 patients with active unilateral Meniere disease refractory to a 3-month trial of medical management.<sup>11</sup> All patients underwent tympanostomy, and patients were additionally randomized to a sham device or a Meniett device. Over the entire four-month trial, there was a significant difference in the total number of episodes of vertigo in the treatment group compared with the control group. However, the difference between the groups was most apparent at one month, while at four months the treatment effect had disappeared almost entirely. Similarly, overall, there was a significant decrease in the frequency of vertigo in the treatment group, but again this difference was most apparent at the one month interval and almost disappeared at four months. This trial was limited by a number of methodologic issues related to the data analysis, and results did not permit drawing conclusions about the impact of this device on patient outcomes.

Gates et al (2006) reported on the 2-year, open-label, follow-up to the 2004 randomized trial.<sup>12</sup> At the end of the randomized phase of the trial, 61 of 67 patients from both the control and active treatment arms were treated with the Meniett device. Vertigo episodes were reported on a daily symptom diary or by a structured telephone interview. Of the 58 patients followed for 2 years, 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. Patients who went into remission had an 80% probability of remaining in remission for the 2 years. This assessment was limited, however, by the lack of a control group followed over the same period.

A multicenter, double-blind, placebo-controlled trial of 63 patients by Thomsen et al (2005) compared micropressure devices with ventilation tubes and sham pressure devices.<sup>13</sup> This trial reported an improvement in functionality (American Academy of Otolaryngology–Head and Neck Surgery criteria) and a trend ( $p=0.09$ ) toward a reduction in episodes of vertigo for the active treatment group compared with controls. The frequency of attacks decreased from 10.5 to 4.0 in the placebo group and from 9.6 to 1.9 in the active group. There were no significant differences in secondary outcome measures (patient's perception of tinnitus, aural pressure, hearing). In addition to a marginal improvement in efficacy over ventilation tubes with sham pressure, this trial was limited by a high dropout rate (37%), lack of intention-to-treat analysis, and short (2-month) monitoring period.

Gurkov et al (2012) reported on a randomized, double-blind, sham-controlled trial with the Meniett device.<sup>14</sup> After a 4-week baseline period, 74 patients underwent ventilation tube placement and were monitored for another 4 weeks. Patients were then randomized to 16 weeks of active or sham treatment (5 minutes, 3 times daily). The primary outcomes were subjective vertigo score, number of definitive vertigo days, and number of sick days as recorded on a daily log over the last four weeks of treatment. Sixty-eight (92%) patients completed the trial. The cumulative vertigo score decreased by 6.5 in the active group and by 1.19 in the sham group ( $p=0.048$ ). The number of vertigo days decreased by 2.42 in the active treatment group and by 0.42 in the sham group ( $p=0.102$ ), and the number of sick days decreased by 2.32 in the active treatment group and increased by 0.58 days in the sham group ( $p=0.041$ ). There was no

significant difference between groups in the vertigo-free days, activity score, hearing level, or slow phase velocity. This trial showed a modest improvement in two of five subjective measures, but not in objective outcome measures, with the Meniett device.

Subsequent to the 2015 Cochrane review, Russo et al (2017) reported on an industry-sponsored, multicenter, double-blind RCT of the Meniett device.<sup>15</sup> A total of 129 patients with Meniere disease not controlled by medical treatment were withdrawn from any vertigo treatment and received placement of a transtympanic tube. Patients (n=97 [75%]) who continued to have symptoms ( $\geq 2$  vertigo episodes during a 6-week period) after placement of a transtympanic tube were randomized to an active or sham device for 6 weeks and then were followed for an additional 6 weeks. The number of vertigo episodes during the baseline period did not differ significantly between groups ( $p=0.07$ ). The trial was powered to detect a 30% difference in vertigo episodes compared with the sham group. Per protocol analysis showed a significant decrease in vertigo episodes in both groups (see Table 1), but no between-group difference ( $p=0.11$ ), suggesting a possible effect of the transtympanic tube. Vertigo-related QOL also did not differ between groups.

**Table 1. Number of Vertigo Episodes**

Treatment Arms	Before Treatment (SEM)	During Treatment (SEM)	After Treatment (SEM)
Active	3.2 (0.4)	2.5 (NR) <sup>a</sup>	1.5 (0.02) <sup>b</sup>
Sham	4.3 (0.6)	2.6 (0.05) <sup>a</sup>	1.8 (0.8) <sup>b</sup>

NR: not reported; SEM: standard error of the mean.

<sup>a</sup>  $p < 0.05$  vs baseline

<sup>b</sup>  $p < 0.005$  vs during treatment.

### Summary of Evidence

For individuals who have Meniere disease who receive transtympanic micropressure therapy (Meniett), the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Six RCTs of positive pressure therapy have been reported, with five specifically investigating the Meniett device. Systematic reviews of these five trials found that micropressure therapy does not result in a greater reduction in vertigo than placebo. The sixth trial also found no significant benefit of the transtympanic micropressure therapy for Meniere disease. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

### Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received through 1 physician specialty society (2 reviewers) and 2 academic medical centers while this policy was under review in 2008. Input was mixed regarding whether this treatment would be considered investigational, as adopted in the policy in 2008.

**Practice Guidelines and Position Statements**

**American Academy of Otolaryngology–Head and Neck Surgery**

The American Academy of Otolaryngology–Head and Neck Surgery (2016) updated its position statement on the use of transtympanic micropressure: “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 disease. Micropressure therapy is best 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.”<sup>16</sup> No supporting evidence was provided.

**National Institute for Health and Care Excellence**

The guidance from the U.K.’s National Institute for Health and Care Excellence (2012) concluded that “[c]urrent evidence on the safety of micropressure therapy for refractory Ménière’s disease is inadequate in quantity. There is some evidence of efficacy, but it is based on limited numbers of patients. Therefore this procedure should only be used with special arrangements....”<sup>17</sup>

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in January 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

**CODING**

**The following codes for treatment and procedures applicable to this policy 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. 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.**

CPT/HCPCS

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

<b>REVISIONS</b>	
08-12-2011	Policy added to the bcbsks.com web site.
08-04-2016	Description section updated
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> <li>▪ Updated coding notations</li> <li>▪ Removed all ICD codes</li> </ul>
	References updated
03-28-2018	Description section updated
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> <li>▪ Updated coding notations</li> </ul>
	References updated

<b>REVISIONS</b>	
05-15-2019	Policy published April 10, 2019. Policy effective May 15, 2019.
	Description section updated
	Rationale section updated
	In Coding section: ▪ Added HCPCS Code: A4638
	References updated

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