



Louisiana

Transtympanic Micropressure Applications as a Treatment of Meniere Disease

Policy # 00505

Original Effective Date: 06/20/2016

Current Effective Date: 06/20/2018

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Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review on available data, the Company considers the use of transtympanic micropressure applications as a treatment of Meniere disease to be **investigational**.*

Background/Overview

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 impede 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 (i.e., 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 the 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 3 minutes, 3 times daily. Treatment continues for as long as patients have vertigo attacks.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 1999, the Meniett^{®†} device (Medtronic Xomed, Jacksonville, FL) was cleared for marketing by the U.S. FDA through the 510(k) process specifically as a symptomatic treatment of Meniere disease.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to 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 a technology, 2 domains are examined: the relevance and the 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 (e.g., continued medical management).

TRANSTYMPANIC MICROPRESSURE THERAPY FOR MENIERE DISEASE

The data submitted to the U.S. FDA as part of the FDA approval process of the Meniett device consisted of a case series of 20 patients. 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. 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.

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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). 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 that 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.

Randomized Controlled Trials

The 3 trials, considered to be of low risk of bias in the Cochrane review, are described next.

Gates et al (2004) reported on 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. All patients underwent tympanostomy, and patients were additionally randomized to a sham device or a Meniett device. Over the entire 4-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 1 month, while at 4 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 1-month interval and almost disappeared at 4 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. 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. 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

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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. 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 4 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 2 of 5 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. 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 (≥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 quality of life 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) ^a	1.5 (0.02) ^b
Sham	4.3 (0.6)	2.6 (0.05) ^a	1.8 (0.8) ^b

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

^a p<0.05 vs baseline

^b 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. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Six RCTs of positive pressure therapy have been reported, with five specifically investigating the Meniett device. Systematic reviews of these 5 trials found that micropressure therapy does not result in a greater reduction in vertigo than placebo. The sixth trial also

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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.

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Policy History

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06/02/2016 Medical Policy Committee review

06/20/2016 Medical Policy Implementation Committee approval. New Policy.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

06/01/2017 Medical Policy Committee review

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06/21/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 06/07/2018 Medical Policy Committee review
 06/20/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 Next Scheduled Review Date: 06/2019

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Code Type	Code
CPT	No codes
HCPCS	A4638, E2120
ICD-10 Diagnosis	H81.01-H81.09

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
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