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Transtympanic Micropressure Applications as a Treatment of Meniere Disease

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Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Transtympanic micropressure applications as a treatment of Meniere disease **are considered not medically necessary.**

Policy Guidelines

None.

Description

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 and 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 to reduce fluid accumulation (i.e., hydrops) and daily vasodilator and diuretic therapy to reduce vestibular symptoms. For patients with symptoms severe enough to require further treatment, there is no widely accepted agreement on which treatment is preferred. Persons who do not respond to these conservative measures may be treated with glucocorticoid therapy and/or gentamicin drops in the ear, as a technique of chemical labyrinthectomy to ablate vestibular function on the affected side. For patients with MD with complete hearing loss in the affected ear, the report suggest treatment with intratympanic gentamycin rather than labyrinthectomy (Grade 2C). (1)

There has been interest in developing a more physiologic treatment approach by applying local transtympanic pressure treatment 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 3 minutes, 3 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 disease. (2)

FDA product code: ETY.

Rationale

Medical policies 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. Food and Drug Administration (FDA) as part of the FDA approval process of the Meniett device consisted of a case series of 20 patients. (2) Other case series have also been published in the peer-reviewed literature, some reporting 2- to 4-year outcomes in patients who had failed medical therapy. (3-9) 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 policy. The remaining literature 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). Three trials were considered to be at low risk of bias, 1 was at unclear risk, and 1 was at high risk of bias. 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 is some evidence that hearing is impaired with this treatment. (10) Another systematic review (2015), which included 4 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. (11)

In 2015, Ahsan and colleagues (12) 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 RCTs 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 ($p\leq0.0001$) 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 2 RCTs were included in the final statistical analysis. Additional 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 2023 Cochrane review, Webster et al. (13) evaluated the benefits and harms of positive pressure therapy versus placebo or no treatment in people with Ménière's disease. Reviewers included three studies of RCTs and quasi-RCTs, with a total of 238 participants. Primary outcomes were: 1) improvement in vertigo (assessed as a dichotomous outcome - improved or not improved), 2) change in vertigo (assessed as a continuous outcome, with a score on a numerical scale) and 3) serious adverse events. Secondary outcomes were: 4) disease-specific health-related quality of life, 5) change in hearing, 6) change in tinnitus and 7) other adverse effects. Outcomes reported at three time points were considered: 3 to < 6 months, 6 to ≤ 12 months and > 12 months. Three studies with a total of 238 participants were included, all of which compared positive pressure using the Meniett device to sham treatment. The duration of follow-up was a maximum of four months. In regard to an improvement in vertigo, a single study assessed whether participants had an improvement in the frequency of their vertigo while using positive pressure therapy, therefore reviewers were unable to draw meaningful conclusions from the results. For change in vertigo, only one study reported on the change in vertigo symptoms using a global score (at 3 to < 6 months), so again reviewers were unable to draw meaningful conclusions from the numerical results. All three studies reported on the change in the frequency of vertigo. The summary effect showed that participants had, on average, 0.84 fewer days per month affected by vertigo (95% confidence interval from 2.12 days fewer to 0.45 days more; 3 studies; 202 participants). However, the evidence on the change in vertigo frequency was very low certainty. None of the included studies provided information on the number of people who experienced serious adverse events. It is unclear whether this is because no adverse events occurred, or whether they were not assessed and reported. Researchers concluded that the evidence for positive pressure therapy for Ménière's disease is very uncertain. There are few RCTs that compare this intervention to placebo or no treatment, and the evidence that is currently available from these studies is of low or very low certainty. This means that there is very low confidence that the effects reported are accurate estimates of the true effect of these interventions. Consensus on the appropriate outcomes to

measure in studies of Ménière's disease is needed (i.e., a core outcome set) in order to guide future studies in this area and enable meta-analyses of the results. This must include appropriate consideration of the potential harms of treatment, as well as the benefits.

Randomized Controlled Trials

In 2004, Gates et al. (14) reported on 4-month results of a randomized, multi-institutional study 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 randomly assigned 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.

In 2006, Gates et al. (15) 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 is 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. (16) 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.

In 2012, Gurkov et al. (17) 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. (18) 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.

UpTodate

An UpToDate article on the evaluation, diagnosis, and management of Meniere disease (last updated December 2024) classifies therapy with a positive pressure pulse generator in the treatment of Meniere disease to be one of several therapies not routinely used or advised due to lack of efficacy and possible evidence of harm. (1)

Summary of Evidence

For individuals who have Meniere disease who receive transtympanic micropressure therapy (Meniett), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. RCTs using positive pressure therapy have been reported. Systematic reviews utilizing the Meniett device found that micropressure therapy does not result in a greater improvement in vertigo than placebo. Another trial also found no significant benefit of the

transtympanic micropressure therapy for Meniere disease. To date, the evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

Practice Guidelines and Position Statements

American Academy of Otolaryngology

The American Academy of Otolaryngology (AAO)-Head and Neck Surgery (2021) updated its 2016 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." (19) No supporting evidence was provided.

In 2020 the AAO Head and Neck Surgery published clinical practice guidelines for Meniere's disease which state "Clinicians should not prescribe positive pressure therapy to patients with Meniere's disease". Recommendation against use is 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. (20)

National Institute for Clinical Excellence

The guidance from the United Kingdom's National Institute for Clinical 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…." (21)

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in January 2025 did not identify any ongoing or unpublished trials that would likely influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	A4638, E2120

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
02/15/2025	Document updated with literature review. Coverage unchanged. No new references added.
03/15/2024	Document updated with literature review. Coverage unchanged. Added one new reference: 12.
10/15/2023	Reviewed. No changes.
04/15/2022	Document updated with literature review. Coverage unchanged. Added references 11, 17, 19; others updated.
02/15/2021	Reviewed. No changes.
04/15/2020	Document updated with literature review. Coverage unchanged. No new references added.
04/15/2019	Reviewed. No changes.

07/01/2018	Document updated with literature review. Coverage unchanged. References 15-16 added.
06/01/2017	Reviewed. No changes.
10/01/2016	Document updated with literature review. The following change was made to Coverage: position changed from “experimental, investigational and/or unproven” to “not medically necessary”.
03/15/2015	Reviewed. No changes.
07/01/2014	Document updated with literature review. The following change was made to Coverage: Transtympanic micropressure applications as a treatment of Meniere's disease are considered experimental, investigational and/or unproven. CPT/HCPCS code(s) updated. Title changed from “Meniett Low Pressure Pulse generator for Menieres Disease”.
04/15/2008	Policy reviewed without literature review; new review date only.
05/15/2006	Revised/updated entire document
12/01/2003	New medical document