Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 3/1/24**
(See policy history boxes for previous effective dates)

Title: Transtympanic Micropressure Applications as a Treatment of Ménière's Disease

Description/Background

MENIERE DISEASE
Ménière's 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 prevent activities of daily living. Therapy is symptomatic in nature and does not address the underlying pathophysiology. 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 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 approach to treatment by applying local pressure treatment to restore the underlying fluid homeostasis. Researchers have noted that symptoms of Ménière's 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 Ménière 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 is continued for as long as patients find themselves in a period of attacks of vertigo.

Transtympanic micropressure treatment for Ménière's disease involves use of a hand-held air pressure generator 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 is continued for as long as patients find themselves in a period of attacks of vertigo.

Regulatory Status:

In 1999, the Meniett device (Medtronic, Minneapolis, MN) received clearance to market through a U.S. Food and Drug Administration (FDA) 510(k) process specifically as a symptomatic treatment of Ménière's disease. The device is currently available through Meniette AG.

Medical Policy Statement

Transtympanic micropressure applications for the treatment of Ménière's disease are experimental/investigational. The use of these devices has not been demonstrated to improve patient clinical outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

E2120 A4638

Rationale

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

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 **PICO** was 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.

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.

Data submitted to the U.S. Food and Drug Administration (FDA) as part of the FDA-approval process consisted of a case series of 20 patients.[1] 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.[2-8] These case series are inadequate to form conclusions due to the lack of a control group, and they will not be discussed further in this review. The remaining literature review will focus on three randomized, controlled trials (RCTs) that have been published.

Systematic Reviews
A 2015 Cochrane review on positive pressure therapy for Ménière's disease included five double blind, placebo-controlled RCTs (total N=265 patient).[9] Three of the studies were considered to be at low risk of bias, one was at unclear risk, and one study 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 Meniette therapy and placebo. This review supports the conclusion that there is no evidence that positive pressure therapy is effective for the treatment of Ménière's disease, and that there is some evidence that hearing is impaired with this treatment. Another systematic review, 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.[10]

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

In 2004, Gates et al reported the 4-month results of a randomized multi-institutional study that enrolled 67 patients with active unilateral Ménière's disease refractory to a 3-month trial of medical management.[11] All patients underwent tympanostomy, and patients were additionally randomly assigned to either a sham device or a Meniett device. Outcomes were assessed using symptom report cards that focused on the severity and frequency of vertigo. Vertigo was assessed on a scale of 1 to 4, and vertigo scored as 2 or higher was considered definitive vertigo. The total number of days of definitive vertigo for all the participants was reported at each month. While an analysis of variance (ANOVA) showed that over the entire 4-month trial, there was a significant difference in the total number of episodes of vertigo in the treatment group compared to the control group, the difference between the groups is 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 study is 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 and colleagues reported a 2-year follow-up of patients from their randomized trial.[12] At the end of the randomized phase of the study, 61 of 67 patients from both the control and active treatment arms were treated openly with the Meniett device; 3 were subsequently lost to follow-up or excluded due to concurrent health problems. Vertigo episodes were reported on a daily symptom diary (44 patients) or by a structured telephone interview (17 patients). Of the 58 patients followed up 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 up over the same period.

A 2005 multicenter, double-blind, placebo-controlled trial of 63 patients compared micropressure devices with ventilation tubes and sham pressure devices.[13] This trial reported an improvement in functionality (American Academy of Otolaryngology–Head and Neck Surgery [AAO-HNS] 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 changes in secondary outcome measures (patient's perception of tinnitus, aural pressure, and hearing). In addition to a marginal improvement in efficacy over placebo, this study is limited by the high dropout rate (37%), lack of intent-to-treat analysis, and short (2-month) monitoring period.

In 2012, Gurkov et al reported a randomized double-blind sham-controlled trial with the Meniett device.[14] 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 patients (92%) completed the study. 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.[15] 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 to 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)[b]	1.5 (0.02)[a]
Sham	4.3(0.6)	2.6(0.05)[b]	1.8 (0.8)[a]

NR: not reported
[a] p<0.005 vs. during treatment
[b] p<0.05 vs. baseline

SUMMARY OF EVIDENCE

For individuals who have Meniere disease who receive Transtympanic micropressure therapy (Meniett), the evidence includes randomized controlled trials and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Five RCTs of positive pressure therapy have been reported, with four trials specifically investigating the Meniett device. Systematic reviews of these trials found that micropressure therapy does not result in a greater improvement in vertigo than placebo. The evidence is sufficient to determine qualitatively that the technology is unlikely to improve the net health outcome.

Ongoing and Unpublished Clinical Trials

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

SUPPLEMENTAL INFORMATION

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

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

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Otolaryngology—Head and Neck Surgery

In 2016, the American Academy of Otolaryngology (AAO)—Head and Neck Surgery 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.”[16] 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.[17]

National Institute for Clinical Excellence (NICE)
In 2012, guidance from NICE concluded that current evidence on the safety of micropressure therapy for refractory Ménière's disease is inadequate in quantity. Although there is some evidence of efficacy, it is based on limited numbers of patients. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit, or research.[18]

Government Regulations
National/Local:

There are no national or local coverage determinations on this topic. Medicare has a fee for procedure code E2120. There are no fees listed for procedure code A4638.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

1. US Food and Drug Administration. FDA 510(k) marketing clearance information for the Meniett device. Available online at: http://www.accessdata.fda.gov/cdrh_docs/pdf/k991562.pdf. Last accessed October 2015.
2. Barbara M, Consagra C, Monini S et al. Local pressure protocol, including Meniett, in the treatment of Ménière's disease: short-term results during the active stage. Acta Otolaryngol 2001; 121(8):939- 44.
3. Densert B, Sass K. Control of symptoms in patients with Ménière's disease using middle ear pressure applications: two years follow-up. Acta Otolaryngol 2001; 121(5):616-21.
4. Gates GA, Green JD. Intermittent pressure therapy of intractable Ménière's disease using the Meniett device: a preliminary report. Laryngoscope 2002; 112(8 pt 1):1489-93.
5. Barbara M, Monini S, Chiappini I et al. Meniett therapy may avoid vestibular neurectomy in disabling Ménière's disease. Acta Otolaryngol 2007; 127(11):1136-41.
6. Dornhoffer JL, King D. The effect of the Meniett device in patients with Ménière's disease: long-term results. Otol Neurotol 2008; 29(6):868-74.
7. Mattox DE, Reichert M. Meniett device for Ménière's disease: use and compliance at 3 to 5 years. Otol Neurotol 2008; 29(1):29-32.
8. Park JJ, Chen YS, Westhofen M. Ménière's disease and middle ear pressure - vestibular function after transtympanic tube placement. Acta Otolaryngol 2009; 129(12):1408-13.
9. Van Sonsbeek, Pullens B, van Benthem PP. Positive pressure therapy for Meniere's disease or syndrome. Cochrane Database Syst Rev. 2015;3:CD008419. PMID 25756795

10. Syed MI, Rutka JA, Hendry J, et al. Positive pressure therapy for Meniere's syndrome/disease with a Meniett device: a systematic review of randomized controlled trials. Clin Otolaryngol. 2015;40(3):197-207. PMID 25346252
11. Gates GA, Green JD, Tucci DL et al. The effects of transtympanic micropressure treatment in people with unilateral Ménière's disease. Arch Otolaryngol Head Neck Surg 2004; 130(6):718-25.
12. Gates GA, Verrall A, Green JD Jr et al. Meniett clinical trial: long-term follow-up. Arch Otolaryngol Head Neck Surg 2006; 132(12):1311-6.
13. Thomsen J, Sass K, Odkvist L et al. Local overpressure treatment reduces vestibular symptoms in patients with Ménière's disease: a clinical, randomized, multicenter, double-blind, placebo-controlled study. Otol Neurotol 2005; 26(1):68-73.
14. Gurkov R, Filipe Mingas LB, Rader T et al. Effect of transtympanic low-pressure therapy in patients with unilateral Ménière's disease unresponsive to betahistine: a randomized, placebo-controlled, double-blinded, clinical trial. J Laryngol Otol 2012; 126(4):356-62.
15. Russo FY, Nguyen Y, De Seta D, et al. Meniett device in Meniere disease: Randomized, double-blind, placebo-controlled multicenter trial. Laryngoscope. Feb 2017;127(2):470-475. PMID 27515294
16. American Academy of Otolaryngology - Head and Neck Surgery. AAO-HNS position on micropressure therapy. Available online at: https://www.entnet.org/resource/position-statement-micropressure-therapy/. Last accessed September 25, 2023.
17. Basura GJ, Adams ME, Monfared A, et al. Clinical practice guideline: Ménière's disease. Otolaryngol Head Neck Surg. 2020; 162(2 suppl):S1-S55. PMID 32267799
18. National Institute for Clinical Excellence (NICE). Micropressure therapy for refractory Ménière's disease. NICE interventional procedure guidance 426. 2012. Available online at: https://www.nice.org.uk/guidance/ipg426/resources/micropressure-therapy-for-refractory-mnires-disease-pdf-1899869632437445. Last accessed September 25, 2023.
19. Blue Cross Blue Shield Association. Transtympanic Micropressure Applications as a Treatment of Ménière's Disease. Medical Policy Reference Manual. Policy #1.01.23, Issue 2:2016, original policy date 4/29/03, last review date April 2020, policy archived.
20. HAYES Health Technology Brief. Meniett Low-Pressure Pulse Generator (Medtronic ENT) for Treatment of Ménière's Disease. Lansdale, PA: HAYES, Inc. Published July 30, 2012, last updated June 26, 2014. Archived in August 2015 as outdated.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 25, 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
12/19/03	12/19/03	1/16/04	Joint policy established
11/1/07	8/21/07	10/31/07	Routine maintenance; policy retired, procedure is obsolete
3/1/09	12/9/08	12/14/08	Policy unretired due to physician inquiry
9/1/10	6/15/10	6/29/10	Routine review of non-established service; added references, updated rationale
11/1/12	8/21/12	8/21/12	Routine maintenance; policy reformatted to mirror BCBSA policy.
3/1/14	12/10/13	1/6/14	Routine maintenance. No change in policy status.
3/1/15	12/12/14	12/29/14	Routine maintenance. No change in policy status.
3/1/16	12/10/15	12/10/15	Routine policy maintenance, references updated. No change in policy status.
3/1/17	12/13/16	12/13/16	Routine policy maintenance, references updated. Deleted Blue Cross Complete reference under coverage determinations.
3/1/18	12/12/17	12/12/17	Routine policy maintenance. Added reference 15. No change in policy status.
3/1/19	12/11/18		Routine policy maintenance, no change in policy status.
3/1/20	12/17/19		Routine policy maintenance, no change in policy status.
3/1/21	12/15/20		Routine policy maintenance, no change in policy status.
3/1/22	12/14/21		Routine policy maintenance, no change in policy status.
3/1/23	12/20/22		Routine policy maintenance, no change in policy status. (ky)
3/1/24	12/19/23		Routine policy maintenance, no change in policy status. Vendor: N/A (ky)

Next Review Date: 4th Qtr. 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: TRANSTYMPANIC MICROPRESSURE APPLICATIONS AS A TREATMENT OF MÉNIÈRE'S DISEASE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.