# Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/12**
**(See policy history boxes for previous effective dates)**

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

### Description / Background

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.

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. 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.

## 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.

## Medical Policy Statement

Transtympanic micropressure applications for the treatment of Ménière's disease are experimental and investigational. They have not been scientifically demonstrated to be as effective as conventional treatment.

## Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

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

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. Other case series have also been published in the peer-reviewed literature. (1-4) However, a randomized, placebo-controlled trial is necessary to distinguish any treatment effect from the intermittent natural history of Ménière's disease.

In 2004, Gates and colleagues published 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. (5) 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 statistical analysis of the data. In particular, repeated-measures ANOVA, which was the primary method used to analyze these data, assumes normal distribution, equal variances and covariances, and equal variances over time (compound symmetry or the so-called sphericity assumption); whether these assumptions were met is unclear from the report. There are a number of "outlier" patients. These outliers would result in the data not being "normally distributed" and also could be influential in the marginally significant p values noted in the study. It is unclear that the "interim power analysis" performed was preplanned or that the trial was intended as an adaptive group sequential design. Whether consideration was given to protecting the type I error rate is also unclear. Given these concerns, results from this trial do not allow 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. (5,6) 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 with 63 patients 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 compared with a group treated with ventilation tubes and sham pressure devices. (7) 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.

A search of the MEDLINE database for the period of March 2007 through June 2008 identified several retrospective case series (12 to 36 subjects) reporting 2- to 4-year outcomes in patients who had failed medical therapy. (8-10) Although these reports suggest a potential benefit of transtympanic micropressure, randomized controlled trials (RCTs) are still needed to evaluate efficacy for this intermittent disease.

Updated searches of the MEDLINE® database from 2009 through August 2011 did not identify any evidence that would change the conclusions of the policy. Only small case series were identified. Notably, one small (n=22) retrospective case series from Germany reported improvement of vertigo in patients with Ménière’s disease with placement of ventilation tubes alone. (11) Patients with ipsilateral middle ear pressure less than -50 decapascals (1

decapascal is equivalent to the pressure of 1.02 mm water) who did not show any response to medical therapy underwent transtympanic tube insertion. The preoperative duration of illness lasted from 6 months to 24 months. At a median of 20 months postoperatively (range, 6–26 months), 68% of patients reported improvement of symptoms. Nine percent of patients reported complete relief of vertigo, 59% reported partial relief, and 32% reported no relief of vertigo. No improvement in vestibular function was found with objective testing.

**Summary**
Overall, the scientific evidence does not permit conclusions concerning the effect of this technology on health outcomes. As illustrated in the trials described above, frequency of vertigo attacks has been reported to decrease with placement of ventilation tubes alone. (7,11) It is therefore not clear if the improvement in vertigo is due to the Meniett device, the insertion of the ventilation tubes, or to variability in disease course. Assessment of the long-term efficacy and adverse effects of this device requires study with appropriately treated controls over an adequate length of time. Therefore, the policy statement remains unchanged.

**Practice Guidelines and Position Statements**
In 2008, the American Academy of Otolaryngology-Head and Neck Surgery issued the following position statement on the use of transtympanic micropressure: "We find that there is convincing and well-controlled medical evidence to support the use of micropressure therapy (such as the Meniett device) in certain cases of Ménière's 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 Ménière's disease." (12) No supporting evidence was provided.

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## Government Regulations

### National:
There is no national coverage determination.

### Local:
There is no local coverage determination.

Medicare has a fee for procedure code E2120. There are no fees listed for procedure code A4638.

### Michigan Department of Community Health:
MDCH does not have any information on micropressure therapy. Procedure codes E2120 and A4638 are not listed on the fee schedule.

*(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.)*

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## 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.fda.gov/cdrh/pdf/k991562.pdf. Last accessed October 2010.
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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. 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.
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6. 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.
7. 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.
8. 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.
9. 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.
10. 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.
11. 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.
12. American Academy of Otolaryngology - Head and Neck Surgery. AAO-HNS position on micropressure therapy. Available online at: http://www.entnet.org/Practice/micropressure.cfm . Last accessed August 2010.


*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 1, 2012, 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. |

Next Review Date: 3rd Qtr, 2013

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

### I. Coverage Determination:

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|---|---|
| **Commercial HMO (includes Self-Funded groups unless otherwise specified)** | Not covered |
| **BCNA (Medicare Advantage)** | Medicare has a fee for procedure code E2120. There are no fees listed for procedure code A4638. |
| **BCN65 (Medicare Complementary)** | Coinsurance covered if primary Medicare covers the service. |
| **Blue Cross Complete of Michigan** | Not covered. |

### 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.