

Transtympanic Micropressure Treatment for Ménière's Disease

Policy MP-032

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.

Description:

Ménière's disease is an idiopathic disorder of the inner ear characterized by episodes of vertigo, fluctuating hearing loss, tinnitus, and ear pressure. Vertigo can be described as a dizzy or spinning sensation. Individuals may experience vertigo as an illusion of motion, vague dizziness, imbalance, disorientation, transient spinning or a sense of swaying or tilting. The vertigo attacks are often unpredictable and incapacitating and may prevent activities of daily living. Therapy addresses symptoms, not the underlying pathophysiology. A low sodium diet and diuretics to reduce fluid accumulation (i.e. hydrops) and pharmacologic therapy to reduce vestibular symptoms may be used as conservative therapy. No therapy is available to restore hearing loss. 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.

There has been interest in developing a more physiologic approach to treatment by applying local transtympanic pressure to restore the underlying fluid homeostasis. The symptoms of Ménière's disease seems to 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's disease involves use of a handheld air low-pressure generator (Meniett device) that delivers intermittent complex pressure pulses.

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Policy Statement and Criteria

1. Commercial Plans

U of U Health Plans does NOT cover the Meniett low-pressure pulse generator for the treatment of Ménière's disease, nausea/vomiting, or tinnitus as it is considered experimental/investigational because its effectiveness has not been established.

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at:

<http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

3. Medicare Plans

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, U of U Health Plans' commercial policies would apply. For the most up-to-date Medicare policies and coverage, please visit their search website at:

<http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#).

Clinical Rationale

The Equilibrium Committee of the American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) revised their recommendation for the use of micropressure therapy (e.g., the Meniett device) in 2016. They found some evidence to support its use in certain cases of Ménière's disease and as a second level therapy when medical treatment has failed or the device represents a largely non-surgical therapy. No specific criteria for treatment are listed. Furthermore, this AAO-HNS position does not appear to be supported by a traditional technology assessment of the device/therapy.

A 2015 systematic review (Syed et al) evaluated the effectiveness of the Meniett device in reducing the frequency and severity of vertigo in Ménière's disease. Four randomized controlled trials (RCTs) compared the effectiveness of the Meniett device in 123 patients versus a placebo device in 114 patients with Ménière's disease, over a follow-up period of 2 weeks to 4 months. The outcome data were dichotomous for all the included trials. An overall 61% of reduction in the frequency of vertigo in both groups were reported. This reduction was not significantly different in any study or meta-analysis between the 2 groups (mean difference in vertigo free days between Meniett and placebo device of 0.77 days over a 1-month period [95 % confidence intervals (CI): -0.82 to 1.83] p = 0.45). No substantial data reported reduction in the severity of vertigo with the Meniett device compared to the placebo device. No evidence was found to support any efficacy for use of the Meniett device in patients with Ménière's disease.

A 2015 Cochrane review (van Sonsbeek et al) evaluated the effects of positive pressure therapy for the symptoms of patients with Ménière's disease. The review included 5 double blind RCTs (total N=265 patients) comparing positive pressure therapy (using the Meniett or a similar device) with placebo in patients with Ménière's. Overall, the risk of bias varied between the 5 trials; 3 trials were considered low risk, 1 was at unclear risk, and 1 was at high risk. In spite of it not being possible to pool data due to heterogeneity in the measurement of outcomes, results on the primary outcome was control of vertigo and the results on secondary outcomes were loss or gain of hearing, severity of tinnitus, perception of aural fullness, functional level, complications or adverse effects, and sick days. However, most trials showed no significant difference in vertigo between positive pressure therapy and placebo. No complications or adverse effects were reported by any study. The positive pressure therapy device itself is minimally invasive. However, in order to use it, a tympanostomy tube needs to be inserted, with the associated risks. The review concluded that the evidence did not support the efficacy of positive pressure therapy for the treatment of Meniere disease and 2 of the studies shown evidence that hearing impairments were worse with this treatment.

Subsequent to the 2015 Cochrane review, in 2017 an industry-sponsored, multicenter, double-blind RCT (Russo et al) evaluated the effectiveness of the portable Meniett device (a low-pressure pulse generator) protocol for total of 129 adult patients with Ménière's disease that included 3 phases; the first phase patients received placement of a transtympanic tube whose vertigo was not controlled by medical treatment and were withdrawn from the trial if symptoms improved; the second phase had a total of 97 patients that passed the first phase and included 6 weeks of treatment with the Meniett or a placebo device (49 received the Meniett device and 48 the placebo device, respectively); and the third phase included removal of the device and a 6 week follow-up period. The number of vertigo episodes during the baseline period did not differ significantly between groups ($p=0.07$). Again the study concluded there was no significant difference between the Meniett and placebo device groups, there was still an improvement of symptoms demonstrated in all patients, which could be explained by an effect of the transtympanic tube.

An UpToDate review on "Ménière's disease" (Moskowitz, 2020) states that "long-term efficacy of overpressure in the control of vertigo is uncertain and hearing conservation should not be expected in all patients choosing this therapy." Additional tympanostomy tube maintenance is required and the device is expensive. Further additional independent, well-designed studies with larger populations along with comparative effectiveness and long-term patient compliance are needed before definitive conclusions can be made regarding the full benefit of this therapy in the general clinical setting.

Applicable Coding

CPT Codes

No applicable codes

HCPCS Codes

E2120 Pulse generator system for tympanic treatment of inner ear endolymphatic fluid

References:

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2. Hong SK, Nam SW, Lee HJ, et al. Clinical observation on acute low-frequency hearing loss without vertigo: The role of cochlear hydrops analysis masking procedure as initial prognostic parameter. *Ear Hear.* 2013;34(2):229-235.

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4. 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
5. 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*. Jun 2015;40(3):197-207. PMID 25346252
6. van Sonsbeek S, Pullens B, van Benthem PP. Positive pressure therapy for Meniere's disease or syndrome. *Cochrane Database Syst Rev*. Mar 10 2015;3(3): CD008419. PMID 25756795
7. Wang, S. J., et al. (2019). "The Clinical Benefit of Device Therapy for Meniere's Disease in Adults: Systematic Review and Meta-Analysis." *J Int Adv Otol* 15(1): 121-129.

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