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Originated Department	Clinical Operations

Transtympanic Micropressure Treatment for Ménière's Disease

Audience
Providers, Members, Brokers, MHC

Purpose

Medical policies provide general support for applying Mountain Health Co-Op member policy document coverage decisions and must reference the member-specific benefit plan document. The terms of the member-specific Policy document may differ from the standard benefit plan on which this medical policy is based. If there is a conflict between a member-specific policy document and the Mountain Health Co-Op medical policy, the member-specific policy document supersedes this medical policy. Any person(s) applying this medical policy must identify member eligibility, the member-specific policy document, and related policies or guidelines before applying this medical policy, including the existence of any state or federal guidance. Mountain Health Co-Op medical policies are designed for informational purposes only and are not an authorization, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the member-specific policy document coverage. Mountain Health Co-Op reserves the sole discretionary right to modify all policies and guidelines at any time.

Definition

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 seem 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 pulses 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.

Policy/Procedure

Commercial Plans/CHIP

Mountain Health Co-Op 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.

1. **Clinical Rationale**
   - **1.1** The Equilibrium Committee of the American Academy of Otolaryngology - Head and Neck Surgery (AAOHNS) 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.
   - **1.2** 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% reduction in the frequency of vertigo in both groups was 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.
   - **1.3** 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 RTCs (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. The primary outcome was control of vertigo and the secondary outcomes were loss or gain of hearing, severity of tinnitus, perception of aural fullness, functional level, complications or adverse effects, and sick days. In spite of it not being possible to pool data due to heterogeneity in the measurement of outcomes, 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 showed evidence that hearing impairments were worse with this treatment.

1.4 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. In the first phase patients whose vertigo was not controlled by medical treatment received placement of a transtympanic tube 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.

1.5 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 Codes

CPT Codes

No applicable codes

HCPCS Codes

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

Vendors

- **Personify**
- **HPS**

References

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Review/Revision/Approval History

Date	Description
07/01/2024	**New Policy**
03/30/2026	**Reviewed and approved by Mountain Health CO-OP Policy Committee**

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