Review Criteria
Georgia Region

KAISER PERMANENTE®

Title:	**MENIETT DEVICE (Positive Pressure Pulse Generator)**		
Department:	QUALITY RESOURCE MANAGEMENT	**Page:**	1 of 5
Section:	UTILIZATION MANAGEMENT	**Policy Number:**	03-33
Type:	( ) New	**Effective Date:**	12/12/2008
	(X) Reviewed **/ Revised** **New request not approved- due to studies do not support its efficacy.** **Patients currently using with good results will be approved to continue use.**	**Date:**	2/27/2017 2/14/2018 2/14/2019 1/3/2020 1/22/2021 1/10/2022 2/28/2023

Purpose
This policy provides the indications and contraindications necessary for the Quality Resource Management staff to make the most appropriate decision related to the medical necessity of the procedure listed.

DIAGNOSIS/CONDITION: ICD-10 H81.09
CPT-4/ HCPCS CODE AND DESCRIPTION: INDICATORS: E2120, A4638

1.0 INDICATIONS
1. Severe Ménière's disease
2. No significant improvement with standard therapy
3. Letter of necessity from the treating ENT physician

2.0 CONTRAINDICATIONS
1. Inadequate trial of standard therapy
2. Considered experimental/investigational with exceptions for difficult cases

3.0 VIEWS OF THE SOUTHEAST PERMANENTE MEDICAL GROUP
- The Meniett device is considered experimental/investigational and studies do not support its use. Members that have been using this device with good response will be allowed to continue use and have replaced if broken. **New request for this device will not be approved since the clinical studies do not support its efficacy**.

- Expert Opinion: TSPMG Otologist Dr. Jonathan Maslan 1/22/2021- Studies do not support the use of these devices but members that are currently using this device with good outcome will be allowed to continue use.

References:

Clinical Practice Guideline: Ménière's Disease

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- **STATEMENT 10. POSITIVE PRESSURE THERAPY: Clinicians should not prescribe positive pressure therapy to patients with Ménière's disease.** *Recommendation against 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.*

  1.1.1 **Action Statement Profile: 10**

- Quality improvement opportunity: Avoidance of ineffective therapy. National Quality Strategy domain: Prevention and Treatment of Leading Causes of Morbidity and Mortality
- Aggregate evidence quality: Grade B, based on a Cochrane SR and 2 small RCTs on Meniett device showing no effect
- Level of confidence in evidence: High
- Benefits: Avoidance of ineffective therapy
- Risk, harm, cost: Patient or physician concerns at the lack of positive pressure therapy as an option if other noninvasive treatments have failed, with remaining options being destructive and/or invasive procedures.
- Benefit-harm assessment: Preponderance of benefit over harms

- Value judgments: While this therapy is generally ineffective, there may be rare patients with limited other options.
- Intentional vagueness: None
- Role of patient preferences: Small
- Exclusions: None
- Policy level: Recommendation against
- Differences of opinion: A small group of panel members felt that some evidence supports the use of the Meniett device and that it could be used in symptomatic patients who have not obtained relief from other nonablative treatments.

4.0 CLINICAL SUMMARY:

There are 3-5 million people in the US with Ménière's disease with 100,000 new cases diagnosed annually. Ménière's disease is a disorder of the inner ear characterized by a surplus of lymph fluid in one of the two lymphatic systems in the endolymphatic system. It is not known what causes the excessive fluid. People with Ménière's disease suffer from episodes of vertigo, tinnitus, a feeling of fullness or pressure in the ear, and fluctuating hearing loss. Symptoms can be quite severe and unpredictable creating a major handicap for some patients. Approximately 70% of patients heal over time with the remaining 30% having progressive disease with no known cure. Approximately, 80% of patients with progressive disease respond to treatment.

Conventional treatment consists of a low sodium diet, diuretic therapy and stress management. If symptoms are not controlled, the following surgical treatments can be considered: intratympanic antibiotics, endolymphatic sac surgery, vestibular neurectomy, or labrinthectomy. Surgery is contraindicated in an "only hearing" ear.

The Meniett™ device uses a hand-held, pressure pulse generator to apply local pressure pulse treatment to the middle ear via an implanted ventilation tube. This treatment is being promoted as a non-invasive, conservative, convenient and cost effective option to effectively control symptoms of Ménière's disease (primarily, for patients who have failed medical therapy). The device is small, portable and easy to use. To initiate treatment, a small ventilation tube is inserted into the eardrum of the patient in a brief outpatient procedure. Low frequency, low amplitude pressure pulses are transmitted via tubing and an earplug into the middle ear so that, theoretically, fluid in inner ear can be evacuated and symptoms relieved. Treatment duration is 5 minutes 3 times per day while symptoms last - usually for two or more weeks. The patient can self-administer treatment after prescription by physician. The FDA approved the Meniett™ device in December 1999.

- In studies that reported adverse events associated with the use of the Meniett™ device, middle ear infections were common (13.5 per cent of patients) as was the replacement of the ventilation tube over time, which is an expected side effect with long-term implantation of ventilation tubes.
- Meniett™ appears to benefit most, but not all patients in terms of reducing the number of vertigo episodes, however it is difficult to ascertain if Meniett™ has a positive effect on the fluctuating hearing levels of Ménière's patients. Treatment with Meniett™ is non-destructive to hearing and has the advantage of preserving cochlear function, which may allow the patient to consider further treatment options in the future. Treatment with Meniett™ may have to be continued in the long term for continued symptom alleviation, however long-term use of the device may be associated with adverse events such as infection and the need for regular replacement of the tube. "
- Studies supporting the use of this device are limited by methodological flaws, including the inability to distinguish treatment effect from that of the natural course of disease, the inability to exclude a participation effect, and the possibility that participants were able to discern which type of device they were assigned. Additional evidence is needed to support the use of the Meniett™ low-pressure pulse generator for the treatment of Ménière's disease. **In summary, additional data is needed from well-designed, large multi-center, randomized, placebo-controlled trials with longer follow-up to establish the efficacy of transtympanic micropressure therapy as treatment for Ménière's disease.**

5.0 REVIEW OF THE LITERATURE:

1. Gates GA, Green JD, Tucci DL, Telian SA. The effects of transtympanic micropressure treatment in people with unilateral Ménière's disease. Arch Otolaryngol Head Neck Surg. 2004 Jun; 130(6):718-25.

2. Gates GA, Verrall A, Green JD Jr, Tucci DL, Telian SA. Meniett™ clinical trial: long-term follow-up. Arch Otolaryngol Head Neck Surg. 2006 Dec; 132(12):1311-6.

3. Mattox DE, Reichert M. Meniett™ device for Ménière's disease: use and compliance at 3 to 5 years. Otol Neurotol. 2008 Jan; 29(1):29-32.

4. Odkvist LM, Arlinger S, Billermark E, Densert B, Lindholm S, Wallqvist J. Effects of middle ear pressure changes on clinical symptoms in patients with Ménière's disease-a clinical multicentre placebo-controlled study. Acta Otolaryngol. 2000; Suppl 543:99-101.

5. Rajan GP, Din S, Atlas MD. Long-term effects of the Meniett™ device in Ménière's disease: the Western Australian experience. J Laryngol Otol. 2005 May; 119:391-5.

6. Stokroos R, Klein Olvink M, Hendrice N, Kingma H. Functional outcome of treatment of Ménière's disease with the Meniett™ pressure generator. Otolaryngol. 2006 Mar; 126(3):254-8.

6.0 REFERENCES:

- **Aetna. Clinical Policy Bulletin: Chronic Vertigo. Last Review 10/2020**
  Aetna considers the Meniett™ low-pressure pulse generator for the treatment of Ménière's disease experimental and investigational because its effectiveness has not been established

Up to Date: Meniere's Disease January 15, 2021: Nonsurgical Treatments: **Positive pressure pulse generator (Meniett)** — **Positive pressure pulse generator (Meniett)**

THERAPIES THAT WE DO NOT USE — There are several therapies used in the treatment of Meniere disease (MD) that we do not routinely use or advise due the lack of efficacy and possible evidence of harm.

●**Positive pressure pulse generator** – Positive pressure ("overpressure") applied to the middle ear may improve fluid exchange in the inner ear. Overpressure treatment, in which a device applies pulses of pressure to the middle ear via a ventilation tube, has been used in patients who failed medical therapy or as an adjunct to medical therapy in patients with functional level 3 or greater (table 4). Maintenance of a patent tympanostomy tube is required for overpressure treatment.
Meta-analyses including prospective studies and randomized trials using overpressure in MD are mixed, with one showing improved vertigo symptoms and hearing [78] and another showing no improvement in vertigo and a possible adverse effect on hearing [79]. In addition, the long-term efficacy of overpressure in the control of vertigo is uncertain, and hearing conservation should not be expected in all patients using this therapy.
In addition, the pulse generator device is expensive and insurance coverage for this procedure is variable. Thus, out-of-pocket costs may be an additional consideration for use of this therapy.

Approval

Luke Beno, MD
Physician Program Director,
Quality Resource Management

1/25/2023
Date

Date_____