

**EFFECTIVE DATE:** 02|16|2010  
**POLICY LAST UPDATED:** 03|05|2019

## OVERVIEW

Transtympanic micropressure applications as a treatment for Meniere'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.

## MEDICAL CRITERIA

Not applicable.

## PRIOR AUTHORIZATION

Not applicable.

## POLICY STATEMENT

### BlueCHiP for Medicare

Transtympanic micropressure applications as a treatment for Meniere's disease is considered not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

### Commercial Products

Transtympanic micropressure applications as a treatment for Meniere's disease is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

## COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

## BACKGROUND

Meniere'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 Meniere'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 Meniere'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 Meniere 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 continues for as long as patients have vertigo attacks.

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. Six randomized controlled trials of positive pressure therapy have been reported, with five specifically investigating the Meniett device. Systematic reviews of these 5 trials found that micropressure therapy does not result in a greater reduction in vertigo than placebo. The sixth trial also found no significant benefit of the transtympanic micropressure therapy for Meniere disease. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

#### **CODING**

The following code is considered not covered for BlueCHIP for Medicare and not medically necessary for Commercial Products:

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

#### **RELATED POLICIES**

Not applicable.

#### **PUBLISHED**

Provider Update, May 2019

Provider Update, February 2019

Provider Update, May 2017

Provider Update, November 2016

Provider Update, May 2015

#### **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](http://www.accessdata.fda.gov/cdrh_docs/pdf/K991562.pdf). Last accessed August, 2013.
2. Barbara M, Consagra C, Monini S et al. Local pressure protocol, including Meniett, in the treatment of Meniere'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 Meniere'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 Meniere'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 Meniere'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. Meniere's disease and middle ear pressure - vestibular function after transtympanic tube placement. *Acta Otolaryngol* 2009; 129(12):1408-13.
9. Gates GA, Green JD, Tucci DL et al. The effects of transtympanic micropressure treatment in people with unilateral Meniere's disease. *Arch Otolaryngol Head Neck Surg* 2004; 130(6):718-25.
10. 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.
11. Gurkov R, Filipe Mingas LB, et al. Effect of transtympanic low-pressure therapy in patients with unilateral Meniere's disease unresponsive to betahistine: a randomised, placebo-controlled, double-blinded, clinical trial. *J Laryngol Otol.* Apr 2012;126(4):356-362. PMID 22365373
12. American Academy of Otolaryngology - Head and Neck Surgery. AAO-HNS position on micropressure therapy. 2012; <http://www.entnet.org/Practice/micropressure.cfm>. Accessed July, 2014.
13. National Institute for Clinical Excellence (NICE). Micropressure therapy for refractory Ménière's disease. NICE interventional procedure guidance 426. 2012; <http://guidance.nice.org.uk/IPG426/Guidance/pdf/English>. Accessed July, 2014.
14. van Sonsbeek S, Pullens B, van Benthem PP. Positive pressure therapy for Meniere's disease or syndrome. *Cochrane Database Syst Rev.* 2015;3:CD008419. PMID 25756795
15. Syed MI, Rutka JA, Hendry J, et al. Positive pressure therapy for Meniere's syndrome/disease with a Meniett device: a systematic review of randomised controlled trials. *Clin Otolaryngol.* Jun 2015;40(3):197-207. PMID 25346252
16. 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

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