

09-E0000-46

Original Effective Date: 12/15/03

Reviewed: 10/24/24

Revised: 11/15/24

Subject: Transtympanic Micropressure Applications as a Treatment of Meniere's Disease

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Meniere disease is an idiopathic disorder of the inner ear characterized by episodes of vertigo, fluctuating hearing loss, tinnitus, and ear pressure. Conservative therapy includes a low sodium diet and diuretics to reduce fluid accumulation (ie, hydrops) and pharmacologic therapy to reduce vestibular symptoms.

There has been interest in developing a more physiologic treatment approach by applying local transtympanic pressure to restore the underlying fluid homeostasis. Researchers have noted that symptoms of Meniere 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 the 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.

Summary and Analysis of Evidence: The American Academy of Otolaryngology-Head and Neck Surgery Clinical Practice Guideline on Ménière's Disease (2020) includes the following recommendation for 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." Patients who have Meniere disease who receive transtympanic micropressure therapy (Meniett), the evidence includes randomized controlled trials (RCTs) and systematic reviews. RCTs of

positive pressure therapy have been reported, with several specifically investigating the Meniett device. Systematic reviews of these trials found that micropressure therapy does not result in a greater reduction in vertigo than placebo. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

POSITION STATEMENT:

Transtympanic micropressure applications as a treatment of Meniere's disease **does not meet the definition of medical necessity**. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

BILLING/CODING INFORMATION:

HCPCS Coding:

A4638	Replacement battery for patient-owned ear pulse generator, each (Noncovered)
E2120	Pulse generator system for tympanic treatment of inner ear endolymphatic fluid (Noncovered)

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

None applicable.

OTHER:

None applicable.

REFERENCES:

1. American Academy of Otolaryngology – Head and Neck Surgery, Position Statement: Micropressure Therapy, 2016; accessed at entnet.org.
2. Basura GJ, Adams ME, et al. Clinical Practice Guideline: Ménière's Disease. Otolaryngol Head Neck Surg. 2020 Apr;162 (2_suppl): S1-S55.

3. Covelli E, Volpini L, et al. Delayed Effect of Active Pressure Treatment on Endolymphatic Hydrops. *Audiol Neurotol*, 22 (1), 24-29, 2017. PMID: 28514787.
4. Gates, G.A., Green, J. D., Tucci, D. L., & Telian, S. A. (2004). The effects of transtympanic micropressure treatment in people with unilateral Ménière's Disease. *Archives of Otolaryngology Head and Neck Surgery*, 130, 718-725.
5. Moskowitz HS, Dinces EA. Meniere disease: Evaluation, diagnosis, and management, 2022. In: UpToDate, Deschler DG, Hussain Z (Eds), UpToDate, Waltham, MA; accessed September 2024 at uptodate.com.
6. National Institute for Health and Care (NICE). Micropressure therapy for refractory Ménière's disease [IPG426]. 2012; accessed at nice.org.
7. 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.
8. Shojaku H, Aoki M, et al. Effects of transtympanic intermittent pressure therapy using a new tympanic membrane massage device for intractable Meniere's disease and delayed endolymphatic hydrops: a prospective study. *Acta Otolaryngol*. 2021 Oct;141(10):907-914. PMID: 34520288.
9. Shojaku H, Takakura H, et al. Long-term effect of transtympanic intermittent pressure therapy using a tympanic membrane massage device for intractable meniere's disease and delayed endolymphatic hydrops. *Acta Otolaryngol*. 2021 Nov;141(11):977-983. PMID: 34689678.
10. Thomason J, Sass K, Odkvist L, Arlinger S. Local overpressure treatment reduced vestibular symptoms in patients with Meniere's disease: a clinical, randomized, multicenter, double-blind, placebo-controlled study. *Oto Neurotol*. 2005 Jan; 26(1): 68-73.
11. U.S. Food and Drug Administration (FDA); accessed at fda.gov.
12. van Esch BF, van der Zaag-Loonen, et al. Interventions for Ménière's disease: an umbrella systematic review. *BMJ Evid Based Med*. 2022 Aug;27(4):235-245. PMID:34750154.
13. 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.
14. Wang SJ, Yang H, et al. 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, April 2019.
15. Webster KE, George B, et al. Positive pressure therapy for Ménière's disease. *Cochrane Database Syst Rev*. 2023 Feb 23;2(2):CD015248.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/24/24.

GUIDELINE UPDATE INFORMATION:

12/15/03	New Medical Coverage Guideline Developed
12/15/04	Scheduled review; code added; maintain investigational.
01/01/06	Scheduled review; investigational status removed; coverage criteria added.
03/15/06	Revisions consisting of adding criteria defining duration for conservative medical treatment.
08/15/07	Reviewed; coverage statement maintained, guideline reformatted, references updated.
02/15/09	Reviewed, position statement maintained, but reformatted; references updated.
12/15/10	Revision; related ICD-10 codes added, formatting changes.

02/15/11	Reviewed; Position Statement unchanged; references updated.
09/15/11	Revision; formatting changes.
05/15/14	Revision; Program Exceptions section updated.
11/01/15	Revision: ICD-9 Codes deleted.
10/01/16	Revision; coding section updated; formatting changes.
07/15/18	Review; position statement revised; description, coding, and references updated.
04/15/20	Review; Position statements maintained and references updated.
05/15/22	Review: Position statement maintained; references updated.
01/01/24	Position statements maintained.
11/15/24	Review: Position statement maintained; description and references updated.