



Louisiana

Transtympanic Micropressure Applications as a Treatment of Meniere Disease

Policy # 00505

Original Effective Date: 06/20/2016

Current Effective Date: 07/13/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of transtympanic micropressure applications as a treatment of Meniere disease to be **investigational**.*

Background/Overview

Meniere Disease

Meniere 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, incapacitating, and may impede activities of daily living. Therapy addresses symptoms, not the underlying pathophysiology. Although the pathophysiology of Meniere 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.

Treatment

Conservative therapy includes a low sodium diet and diuretics to reduce fluid accumulation (ie, 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 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

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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 three minutes, three times daily. Treatment continues for as long as patients have vertigo attacks.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 1999, the Meniett[®] device (Medtronic Xomed, Jacksonville, FL) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process specifically as a symptomatic treatment of Meniere disease.

Rationale/Source

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. Transtympanic pressure treatment has been proposed as an alternative treatment for Meniere disease. This treatment involves the use of a handheld device (eg, Meniett) that delivers air pressure pulses to the ear.

For individuals who have Meniere disease who receive transtympanic micropressure therapy (Meniett), the evidence includes randomized controlled trials and systematic reviews. The 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 five 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.

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Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received through 1 physician specialty society (2 reviewers) and 2 academic medical centers while this policy was under review in 2008. Input was mixed regarding whether this treatment would be considered investigational, as adopted in the policy in 2008.

Practice Guidelines and Position Statements

American Academy of Otolaryngology–Head and Neck Surgery

The American Academy of Otolaryngology–Head and Neck Surgery (2016) updated its position statement on the use of transtympanic micropressure: “We find that there is some medical evidence to support the use of micropressure therapy (such as the Meniett device) in certain cases of Meniere disease. Micropressure therapy is best used as a second level therapy when medical treatment has failed. The device represents a largely non-surgical therapy that should be available as one of the many treatments for Meniere’s disease.” No supporting evidence was provided.

National Institute for Health and Care Excellence

The guidance from the U.K.’s National Institute for Health and Care Excellence (2012) concluded that “[c]urrent evidence on the safety of micropressure therapy for refractory Ménière’s disease is inadequate in quantity. There is some evidence of efficacy, but it is based on limited numbers of patients. Therefore this procedure should only be used with special arrangements....”

U.S. Preventive Services Task Force Recommendations

Not applicable.

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Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in January 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Transtympanic Micropressure Applications as a Treatment of Meniere Disease”, Policy 1.01.23, Archived April 2020.
2. U.S. Food and Drug Administration (FDA). FDA 510(k) marketing clearance information for the Meniett device (K991562). 1999; http://www.accessdata.fda.gov/cdrh_docs/pdf/K991562.pdf.
3. 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.* Dec 2001;121(8):939-944. PMID 11813899
4. Densert B, Sass K. Control of symptoms in patients with Meniere's disease using middle ear pressure applications: two years follow-up. *Acta Otolaryngol.* Jul 2001;121(5):616-621. PMID 11583396
5. Gates GA, Green JD, Jr. Intermittent pressure therapy of intractable Meniere's disease using the Meniett device: a preliminary report. *Laryngoscope.* Aug 2002;112(8 Pt 1):1489-1493. PMID 12172267
6. Barbara M, Monini S, Chiappini I, et al. Meniett therapy may avoid vestibular neurectomy in disabling Meniere's disease. *Acta Otolaryngol.* Nov 2007;127(11):1136-1141. PMID 17851896
7. Dornhoffer JL, King D. The effect of the Meniett device in patients with Meniere's disease: long-term results. *Otol Neurotol.* Sep 2008;29(6):868-874. PMID 18617868
8. Mattox DE, Reichert M. Meniett device for Meniere's disease: use and compliance at 3 to 5 years. *Otol Neurotol.* Jan 2008;29(1):29-32. PMID 18199955
9. Park JJ, Chen YS, Westhofen M. Meniere's disease and middle ear pressure: vestibular function after transtympanic tube placement. *Acta Otolaryngol.* Dec 2009;129(12):1408-1413. PMID 19922090

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10. 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
11. 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
12. Gates GA, Green JD, Jr., Tucci DL, et al. The effects of transtympanic micropressure treatment in people with unilateral Meniere's disease. *Arch Otolaryngol Head Neck Surg*. Jun 2004;130(6):718-725. PMID 15210552
13. Gates GA, Verrall A, Green JD, Jr., et al. Meniett clinical trial: long-term follow-up. *Arch Otolaryngol Head Neck Surg*. Dec 2006;132(12):1311-1316. PMID 17178941
14. Thomsen J, Sass K, Odqvist L, et al. Local overpressure treatment reduces vestibular symptoms in patients with Meniere's disease: a clinical, randomized, multicenter, double-blind, placebo-controlled study. *Otol Neurotol*. Jan 2005;26(1):68-73. PMID 15699722
15. Gurkov R, Filipe Mingas LB, Rader T, 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
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
17. American Academy of Otolaryngology - Head and Neck Surgery. Position statement: micropressure therapy. 2016; <http://www.entnet.org/Practice/micropressure.cfm>.
18. National Institute for Health and Care (NICE). Micropressure therapy for refractory Meniere's disease [IPG426]. 2012; <http://guidance.nice.org.uk/IPG426/Guidance/pdf/English>.

Policy History

Original Effective Date: 06/20/2016

Current Effective Date: 07/13/2020

06/02/2016 Medical Policy Committee review

06/20/2016 Medical Policy Implementation Committee approval. New Policy.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

06/01/2017 Medical Policy Committee review

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- 06/21/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 06/07/2018 Medical Policy Committee review
- 06/20/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 06/06/2019 Medical Policy Committee review
- 06/19/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 12/11/2019 Coding update
- 06/04/2020 Medical Policy Committee review
- 06/10/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	A4638, E2120
ICD-10 Diagnosis	H81.01-H81.09 Codes added eff 1/1/2020: H81.41-H81.49

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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