

Corporate Medical Policy

Transtympanic Micropressure Applications as a Treatment of Meniere's Disease

File Name: transtympanic_micropressure_applications_as_a_treatment_of_menieres_disease
Origination: 8/12/2004
Last CAP Review: 8/2011
Next CAP Review: 8/2012
Last Review: 8/2011

Description of Procedure or Service

Transtympanic micropressure 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.

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.

In 1999, the Meniett device (Medtronic) received clearance to market through a U.S. Food and Drug Administration (FDA) 510(k) process specifically as a symptomatic treatment of Meniere's disease.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Transtympanic Micropressure Applications as a Treatment of Meniere's disease are considered investigational. BCBSNC does not provide coverage for investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Transtympanic Micropressure Applications as a Treatment of Meniere's Disease

When Transtympanic Micropressure Applications as a Treatment of Meniere's disease are covered

Not applicable.

When Transtympanic Micropressure Applications as a Treatment of Meniere's disease are not covered

Transtympanic micropressure applications as a treatment of Meniere's disease are considered investigational.

Policy Guidelines

Data submitted to the U.S. Food and Drug Administration (FDA) as part of the FDA-approval process consisted of a case series of 20 patients. Other case series have also been published in the peer-reviewed literature. However, a randomized, placebo-controlled trial is necessary to distinguish any treatment effect from the intermittent natural history of Meniere's disease. Overall, the scientific evidence does not permit conclusions concerning the effect of transtympanic micropressure applications on health outcomes. According to the published literature, frequency of vertigo attacks has been reported to decrease with placement of ventilation tubes alone. It is therefore not clear if the improvement in vertigo is due to the Meniett device, the insertion of the ventilation tubes, or to variability in disease course. Assessment of the long-term efficacy and adverse effects of this device requires study with appropriately treated controls over an adequate length of time. Therefore, the policy statement remains unchanged.

In 2008, the American Academy of Otolaryngology-Head and Neck Surgery issued the following position statement on the use of transtympanic micropressure: "We find that there is convincing and well-controlled medical evidence to support the use of micropressure therapy (such as the Meniett device) in certain cases of Meniere's 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: A4638, E2120

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration, Center for Devices and Radiological Health, 510 (k)s Final Decisions Rendered for December 1999; Meniett 20-K991562. Retrieved from <http://www.fda.gov/cdrh/pdf/k991562.pdf>

BCBSA Medical Policy Reference Manual, 1.01.23; 4/29/03

Transtympanic Micropressure Applications as a Treatment of Meniere's Disease

BCBSA Medical Policy Reference Manual, 1.01.23; 12/17/03

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.23, 4/16/04.

Specialty Matched Consultant Advisory Panel - 6/2004

ECRI Target Report #845 (2003, September) Content current as of: March, 2005. Transtympanic micropressure treatment for Meniere's disease. Retrieved on March 7, 2006 from http://www.target.ecri.org/summary/detail.aspx?e=6&doc_id=1756&q=Meniett+device&anm.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.23, 8/17/05.

Specialty Matched Consultant Advisory Panel - 6/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.23, 4/17/07.

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.

Thomsen J, Sass K, Odkvist 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 2005; 26(1):68-73.

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.

Specialty Matched Consultant Advisory Panel - 6/23/08

American Academy of Otolaryngology - Head and Neck Surgery. AAO-HNS position on micropressure therapy. Available at: <http://www.entnet.org/Practice/micropressure.cfm>. Last viewed July 2008.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.23, 10/06/09

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.23, 10/08/2010

Policy Implementation/Update Information

- 8/12/04 Notification of new policy titled "Transtympanic Micropressure Applications as a Treatment of Meniere's Disease". Specialty Matched Consultant Advisory Panel review. Transtympanic micropressure applications as a treatment of Meniere's Disease is considered investigational. Notification given 8/12/04. Effective date 10/14/04.
- 9/18/06 Additional information added to Description section. Policy Guidelines and Reference sources added. (pmo)
- 7/28/08 Reference sources added. Specialty Matched Consultant Advisory Panel review 6/23/08. "Policy Guidelines" section updated. (pmo)
- 6/22/10 Policy Number(s) removed. (amw)
- 7/6/2010 Description section revised. Specialty Matched Consultant Advisory Panel review 5/24/10. No change to policy statement. (adn)
- 9/13/11 Rationale in the Policy Guidelines section updated. Specialty Matched Consultant Advisory Panel review 8/31/11. (adn)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.