



Corporate Medical Policy

Transtympanic Micropressure Applications as a Treatment of Meniere's Disease

File Name: transtympanic_micropressure_applications_as_a_treatment_of_menieres_disease
Policy Number: DME0243
Origination: 8/12/2004
Last Review: 06/2008
Next Review: 06/2010

Description of Procedure or Service

Meniere's disease is an chronic, incurable vestibular (inner ear) disorder characterized by a feeling of dizziness or a "spinning" sensation (rotational vertigo) associated with hearing loss, a roaring or ringing in the ears (tinnitus), a feeling of fullness or pressure in the ears, nausea and vomiting. The vertigo attacks are often unpredictable and incapacitating. The attacks can last between 20 minutes and a day or more. The cause of the disease is not precisely known, but it is thought that the primary problem is in the endolymphatic sac, an organ in the inner ear, which maintains the level of fluid (endolymph) in the hearing and balance canals of the inner ear. Meniere's disease thus produces a recurring set of symptoms as a result of abnormally large amounts of endolymph collecting in the inner ear. Standard medical treatments include dietary restrictions (e.g., salt, caffeine, chocolate, alcohol, nicotine, water), diuretics ("water pills") to attempt to reduce the volume of fluid within the ear, steroids, and anti-allergy therapies, along with medications for episodic nausea, vertigo, and anxiety. Recovery can occur spontaneously, or the disorder can become chronic and disabling. Different medical and surgical methods have been tried to reduce the endolymphatic pressure in Meniere's disease. Surgical treatments for Meniere's disease are reserved for patients for whom medical management has failed.

Local pressure therapy is a new treatment that is intended to alleviate the symptoms of Meniere's disease. In 1999, the Meniett device (Medtronic Xomed) 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. The FDA's 510(k) process usually does not require clinical trials to prove that the medical device is safe or effective. The device consists of a hand-held air pressure generator that delivers intermittent complex pressure pulses. The application of low-frequency, low-amplitude pressure pulses of air increases pressure within the middle ear, and consequently there is a reduction of the excess fluid in the inner ear. Use of the device consists of two phases: 1. a conventional ventilation tube is surgically placed in the eardrum of the ear to be treated; and 2. patients are instructed to place an ear-cuff in the external ear canal to minimize leakage to the external environment. Patients are instructed to treat themselves three times daily for three minutes each time. The treatment is continued for as long as patients find themselves in a period of attacks of vertigo. During periods of remission, no treatment is needed.

Policy

BCBSNC will not provide coverage for Transtympanic Micropressure Applications as a Treatment of Meniere's disease because it is considered investigational. BCBSNC does not cover investigational services.

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Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

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

Not applicable.

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

It is not covered. It is considered investigational and BCBSNC does not cover investigational services.

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 with larger sample sizes, appropriate controls, and longer-term follow-up are necessary to distinguish any treatment effect from the intermittent natural history of Meniere's disease. In 2004, Gates and colleagues published the 4-month results of a randomized multi-institutional study that enrolled 67 patients with active unilateral Meniere's disease refractory to a 3-month trial of medical management. All patients underwent tympanostomy, and patients were additionally randomized to either a sham device or a Meniett device. Outcomes were assessed using symptom report cards that focused on the severity and frequency of vertigo. Vertigo was assessed on a scale of 1 to 4, and vertigo scored as 2 or higher was considered definitive vertigo. The total number of days of definitive vertigo for all the participants was reported at each month. While an ANOVA analysis showed that over the entire 4-month trial there was a significant difference in the total number of episodes of vertigo in the treatment group compared to the control group, the difference between the groups is most apparent at 1 month, while at 4 months the treatment effect has disappeared almost entirely. Similarly, overall, there was a significant decrease in the frequency of vertigo in the treatment group, but again this difference was most apparent at the 1-month interval and almost disappeared at 4 months. No statistical analysis is provided for the 1-month interval. It is difficult to interpret these results, and longer term follow-up is required. For example, the results could suggest that the device is only associated with a short-term improvement in vertigo, or a delayed placebo effect in the control group, or perhaps reflect the cyclical nature of the natural history of Meniere's disease. In the control group, the total number of days with definitive vertigo initially declines slowly, then increases again, and then sharply declines at 4 months. If these changes in vertigo are due to the cyclical nature of Meniere's disease, one might expect to see the number of vertigo days again rise in the control group in subsequent months.

A multicenter, double-blind, placebo-controlled trial with 63 patients reported an improvement in functionality (American Academy of Otolaryngology–Head and Neck Surgery [AAO-HNS] criteria) and a trend ($p=0.09$) toward a reduction in episodes of vertigo compared with a group treated with ventilation tubes and sham pressure devices. The frequency of attacks decreased from 10.5 to 4.0 in the placebo group and from 9.6 to 1.9 in the active group. There were no changes in secondary outcome measures (patient's perception of tinnitus, aural pressure, and hearing). In addition to a marginal improvement in efficacy over placebo, this study is limited by the high dropout rate (37%), lack of intent-to-treat analysis, and short (2-month) monitoring period.

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Gates and colleagues reported 2-year follow-up of patients from their randomized trial. At the end of the randomized phase of the study, 61 of 67 patients from both the control and active treatment arms were treated openly with the Meniett device; 3 were subsequently lost to follow-up or excluded due to concurrent health problems. Vertigo episodes were reported on a daily symptom diary (44 patients) or by a structured telephone interview (17 patients). Of the 58 patients followed up for 2 years, 14 (24%) dropped out to seek alternative surgical treatment, 5 (9%) showed little or no improvement, and 39 (67%) reported being in remission or substantially improved. For patients who went into remission, there was an 80% probability of remaining in remission for the 2 years. This assessment is limited, however, by the lack of a control group with ventilation tubes followed up over the same period.

These studies do not provide adequate support for a change in the existing policy statement. As illustrated in the trial described above, 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 reported by Gates and colleagues at the 2-year follow-up is due to the Meniett device, the insertion of the ventilation tubes, or to variability in disease course. In addition, a common problem with ventilation tubes is plugging requiring reinsertion of the tube, and an increase in middle ear infections. Assessment of the long-term efficacy and adverse effects of this device will require study with appropriately treated controls over an adequate length of time.

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.

Policy Key Words

Key Words: Meniett device, ringing in ears, Meniere's Disease, ear pressure, DME0243

Medical Term Definitions

N/A

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

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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.

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Specialty Matched Consultant Advisory Panel - 6/2006

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Specialty Matched Consultant Advisory Panel - 6/23/08

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.
- 7/28/08 Reference sources added. Specialty Matched Consultant Advisory Panel review 6/23/08. "Policy Guidelines" section updated.

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.

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