BlueCross BlueShield of Alabama

Name of Policy:

Transtympanic Micropressure Applications as a Treatment of Ménière's Disease

Policy #: 092
Category: DME

Latest Review Date: October 2014
Policy Grade: A

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Transtympanic micropressure treatment for Meniere's disease involves use of a handheld 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 three minutes, three 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.

Policy:

Transtympanic micropressure applications as a treatment of Ménière's disease does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

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, some reporting two- to four-year outcomes in patients who had failed medical therapy. These case series are inadequate to form conclusions due to the lack of a

control group, and they will not be discussed further in this review. The remaining literature review will focus on three randomized, controlled trials (RCTs) that have been published. The most recent literature review was performed through August 2014.

The first RCT was published in 2004 by Gates and colleagues. This trial reported the four-month results of a randomized multi-institutional study that enrolled 67 patients with active unilateral Meniere's disease refractory to a three-month trial of medical management. All patients underwent tympanostomy, and patients were additionally randomly assigned 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 one to four, and vertigo scored as two 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 analysis of variance (ANOVA) showed that over the entire four-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 was most apparent at one month, while at four months the treatment effect had 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 one-month interval and almost disappeared at four months. This study is limited by a number of methodologic issues related to the statistical analysis of the data. In particular, repeated-measures ANOVA, which was the primary method used to analyze these data, assumes normal distribution, equal variances and covariances, and equal variances over time (compound symmetry or the so-called sphericity assumption); whether these assumptions were met is unclear from the report. There are a number of "outlier" patients. These outliers would result in the data not being "normally distributed" and also could be influential in the marginally significant p values noted in the study. It is unclear that the "interim power analysis" performed was preplanned or that the trial was intended as an adaptive group sequential design. Whether consideration was given to protecting the type I error rate is also unclear. Given these concerns, results from this trial do not allow drawing conclusions about the impact of this device on patient outcomes.

In 2006, Gates and colleagues reported two-year open-label follow-up from this 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 with the Meniett device; three 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 two years, 14 (24%) dropped out to seek alternative surgical treatment, five (9%) showed little or no improvement, and 39 (67%) reported being in remission or substantially improved. Patients who went into remission had an 80% probability of remaining in remission for the two years. This assessment is limited, however, by the lack of a control group followed up over the same period.

A 2005 multicenter, double-blind, placebo-controlled trial of 63 patients compared micropressure devices with ventilation tubes and sham pressure devices. This trial 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 for the active treatment group compared with controls. 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 ventilation tubes with sham pressure, this study is limited by the high dropout rate (37%), lack of intent-to-treat analysis, and short (two-month) monitoring period.

In 2012, Gurkov et al reported a randomized double-blind sham-controlled trial with the Meniett device. After a four-week baseline period, 74 patients underwent ventilation tube placement and were monitored for another four weeks. Patients were then randomized to 16 weeks of active or sham treatment (five minutes, three times daily). The primary outcomes were subjective vertigo score, number of definitive vertigo days, and number of sick days as recorded on a daily log over the last four weeks of treatment. Sixty-eight patients (92%) completed the study. The cumulative vertigo score decreased by 6.5 in the active group and by 1.19 in the sham group (p=0.048). The number of vertigo days decreased by 2.42 in the active treatment group and by 0.42 in the sham group (p=0.102), and the number of sick days decreased by 2.32 in the active treatment group and increased by 0.58 days in the sham group (p=0.041). There was no significant difference between groups in the vertigo-free days, activity score, hearing level, or slow phase velocity. This double-blind sham-controlled study shows a modest improvement in two of five subjective measures, but not in objective outcome measures, with the Meniett device. It is also limited by the relatively short (four-month) follow-up period.

Summary

Currently three randomized controlled trials of the Meniett device have been published. Results of the two most recent trials show a marginal improvement at short-term follow-up in some subjective outcome measures when compared with insertion of ventilation tubes and use of a sham device. Other primary and secondary outcome measures, including objective measures, were not improved. Analysis of these data on a per-patient level, i.e., by reporting the percent of responders who achieve a minimal clinically important difference on each outcome measure, would allow greater certainty on whether improvements with this device are clinically significant. At this time, the scientific evidence does not permit conclusions concerning the effect of this technology on health outcomes. Therefore, it is considered investigational.

Practice Guidelines and Position Statements

In 2012, the American Academy of Otolaryngology-Head and Neck Surgery updated their 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.

In 2012, guidance from the United Kingdom's National Institute for Clinical Excellence (NICE) concluded that current evidence on the safety of micropressure therapy for refractory Meniere's disease is inadequate in quantity. Although there is some evidence of efficacy, it is based on limited numbers of patients. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit, or research.

Key Words:
Ménière's disease, Meniett, low-pressure pulse generator, transtympanic micropressure

Approved by Governing Bodies:
In 1999, the Meniett device (Medtronic Xomed, Inc., Jacksonville, Florida) received 510(k) approval by the U.S. Food and Drug Administration (FDA) as a symptomatic treatment of Ménière's disease.

Benefit Application:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

Coding:
Effective for dates of service on or after January 1, 2004:

HCPCS codes:	**A4638**	Replacement battery for patient owned ear pulse generator, each
	E2120	Pulse generator system for tympanic treatment of inner endolymphatic fluid
	E1399	Durable medical equipment, miscellaneous

References:

1. American Academy of Otolaryngology-Head and Neck Surgery. Ménière's disease. www.entnet.org/healthinfo/balance/meniere.cfm.
2. American Academy of Otolaryngology – Head and Neck Surgery. AAO-HNS position on micropressure therapy. Available at www.entnet.org/Practice/micropressure.cfm. Last accessed August, 2013.
3. Barbara M, Consagra C, et al. Local pressure protocol, including Meniett, in the treatment of Ménière's disease: Short-term results during the active stage. Acta Otolaryngology, December 2001; 121(8): 939-44.
4. 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.
5. Densert B and Sass K. Control of symptoms in patients with Ménière's disease using middle ear pressure applications: Two years follow up, Acta Otolaryngology, 2001; 121: 616-621.
6. Dornhoffer JL and King D. The effect of the Meniette device in patients with Ménière's disease: Long-term results. Otol Neurotol, September 2006; 29(6): 868-874.

7. Gates George A, et al. The effects of transtympanic micropressure treatment in people with unilateral Ménière's disease, Arch Otolaryngology Head Neck Surgery 2004; 130: 718-725.
8. Gates GA. Treatment of Ménière's disease with the low-pressure pulse generator (Meniett device). Expert Review of Medical Devices, September 2005, Vol. 2, No. 5, pp. 533-537.
9. Gates GA and Green Jr. JD. Intermittent pressure therapy of intractable Ménière's disease using the Meniett device: A preliminary report, Laryngoscope, August 2002; 112(8 Pt 1): 1489-93.
10. Gates GA, Verrall A, et al. Meniett Clinical Trial: Long-term Follow-up. Arch Otolaryngol Head Neck Surg, December 2006, Vol. 132, pp. 1311-1316.
11. 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 2012; 126(4):356-62.
12. Mattox DE and Reichert M. Meniett device for Ménière's disease: Use and compliance at 3 to 5 years. Otol Neurotol, January 2008; 29(1): 29-32.
13. National Institute for Clinical Excellence (NICE). Micropressure therapy for refractory Ménière's disease. NICE interventional procedure guidance 426. 2012. Available online at: //guidance.nice.org.uk/IPG426/Guidance/pdf/English. Last accessed August, 2013.
14. Odkvist LM. Effects of middle ear pressure changes on clinical symptoms in patients with Ménière's disease—a clinical multicentre placebo-controlled study, Acta Otolaryngology Suppl, January 2000; 543: 99-101.
15. Odkvist L. Pressure treatment versus gentamicin for Ménière's disease, Acta Otolaryngology, 2001; 121: 266-268.
16. Park JJ, Chen YS and Westhofen M. Ménière's disease and middle ear pressure – vestibular function after transtympanic tube placement. Acta Otolaryngol, March 2009; 129(12):1408-13.
17. National Institute on Deafness and Other Communication disorders. Health information: Ménière's disease. www.nidcd.nih.gov/health/balance/meniere.asp.
18. Rajan GP, et al. Long term effects of the Meniett device in Ménière's disease: The Western Australian experience. Journal of Laryngology and Otology, May 2005; 119(5): 391-395.
19. Thomsen J. Local overpressure treatment reduces vestibular symptoms in patients with Ménière's disease: A clinical, randomized multicenter, double-blind, placebo-controlled study. Otology/Neurotology, January 2005; 26(1): 68-73.
20. U.S. Food and Drug Administration. FDA 510(k) marketing clearance information for the Meniett device. Available online at www.accessdata.fda.gov/cdrhdocs /pdf/K991562.pdf. Last accessed August, 2013.
21. U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) 510(k) approvals. www.fda.gov/cdrh/pdf/k991562.pdf.
22. U.S. Food and Drug Administration (FDA). Pascal medical AB 510(k) summary. December 28, 1999.
23. Vestibular Disorders Association. Ménière's disease.
24. www.vestibular.org/menieres.html.
25. www.meniett.com/stripcontent.php?parent_file=/device.html.
26. www.meniett.com/stripcontent.php?parent_file=/medical_treatment.html.

Policy History:

Medical Policy Group, January 2003 **(1)**
Medical Policy Administration Committee, February 2003
Available for comment February 6-March 24, 2003
Medical Policy Group, September 2006 **(1)**
Medical Policy Group, September 2008 **(1)**
Medical Policy Group, September 2010 **(1)**
Medical Policy Administration Committee, September 2010
Medical Policy Group, October 2011 **(1):** Update to Key Points; no change to policy statement
Medical Policy Group, October 2012 **(1)**: 2012 Update to Key Points and References
Medical Policy Panel, October 2013
Medical Policy Group, October 2013 **(3)**: 2013 Updates to Description, Key Points and References; no change in policy statement
Medical Policy Panel, October 2014
Medical Policy Group, October 2014 **(5):** Literature search from August 2014 did not yield any updates to policy.
