



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Transtympanic Micropressure Device for Ménière's Disease (e.g., Meniett™ Device)**

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Aural Rehabilitation
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 Tinnitus Treatment Services and Devices
 Vestibular Rehabilitation and Particle Repositioning Maneuvers

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

CIGNA does not cover the use of a transtympanic micropressure device (e.g., Meniett™ Device) for any condition because it is considered experimental, investigational or unproven.

CIGNA does not cover tympanostomy with tube placement when performed solely in preparation for the use of a transtympanic micropressure device, because it is considered not medically necessary.

General Background

Ménière's disease (also called idiopathic endolymphatic hydrops) is a disorder of the inner ear. Although the cause is unknown, the disorder probably results from an abnormally large amount of fluid (called endolymph) collecting in the inner ear. The symptoms of Ménière's disease include episodic vertigo (i.e., a sensation of dizziness or spinning), hearing loss, tinnitus (i.e., ringing in the ears), and a sensation of fullness in the affected ear.

Conservative treatment for Ménière's disease includes lifestyle modifications, such as following a low-salt diet; avoiding caffeine, smoking, and alcohol; and maintaining regular sleeping and eating schedules. Medications that may be beneficial include diuretics, anti-vertigo medications and anti-emetics (for nausea and vomiting). Vestibular rehabilitation has also been proposed as a treatment, but its efficacy has not been supported by peer-reviewed, published literature. If conservative treatment (e.g., low-salt diet) is not successful in controlling

symptoms, other types of therapy may be proposed such as an endolymphatic shunt or decompression procedure. These procedures may resolve vertigo in 50–75% of patients while improving and/or stabilizing hearing in 55% of patients. Complications include: hearing loss in 1–2% of individuals, wound infection, cerebrospinal fluid (CSF) leak, meningitis, and facial paralysis. Selective neurectomy has also been proposed as a treatment and consists of the sectioning of the eighth cranial nerve. Some series report that this results in complete resolution of vertigo in 95% of patients. Complications include: temporary facial weakness, total hearing loss (5%), subdural hematoma, CSF leak, and meningitis. This procedure, however, has been replaced in popularity by the peripheral destructive procedures (e.g., labyrinthectomy). Chemical or surgical labyrinthectomy has also been proposed for treatment of vertigo (resolution of symptoms is greater than 90%) but results in permanent hearing loss in the affected ear.

The use of a transtympanic micropressure device/low-pressure pulse generator (i.e., Meniett™) (Medtronic Xomed, Jacksonville, FL) has been proposed as an alternative to surgery. The device is prescribed by a physician and delivers low-frequency, low-amplitude pressure pulses within the range of 0–20 centimeter (cm) H₂O to the middle ear via a close-fitting ear cuff and tympanostomy tube. Its mode of action is thought to be transmission of the pulses to the inner ear, promoting the flow of endolymph out of the cochlea, alleviating the hydrops and relieving symptoms. The tympanostomy tube is inserted under local anesthetic in the office setting. The patient then uses the device at home three times per day for approximately three minutes per session. The patient discontinues use when symptoms remit.

U.S. Food and Drug Administration (FDA)

In December 1999, Pascal Medical AB (Sweden) received 510(k) approval from the FDA for the Meniett Low-Pressure Pulse Generator. In 2001, Medtronic Xomed, Inc. (Jacksonville, FL) purchased the device from Pascal Medical. The Meniett Low-Pressure Pulse Generator is classified as a Class II device and is indicated for the symptomatic treatment of Ménière's disease.

Literature Review

There are several small randomized, controlled trials evaluating the Meniett device. Odkvist et al. (2000) estimated the effect of overpressure treatment on rotary vertigo, dizziness, aural fullness, tinnitus and hearing function. Fifty-six patients underwent either pressure treatment or placebo treatment for two weeks. The authors discuss a significant improvement in vertigo, tinnitus and functional profile, but provide no statistical evidence of how they reached this conclusion. The mean differences in the hearing threshold levels before and after treatment with active Meniett device use were significantly different from zero at the frequencies 500Hz ($p < 0.03$) and 1kHz ($p < 0.01$), but not at higher frequencies. The lack of statistical evidence and the small patient population does not permit conclusions regarding the efficacy of the Meniett device in reducing the symptoms associated with Ménière's disease. Gates et al. (2004) evaluated 62 patients, all undergoing placement of tympanostomy tubes. The patients then received treatment with either the Meniett device or a mock device that produced the same noise but did not produce air pulses. The treatment group experienced reduced frequency and intensity of vertigo compared to the control group, although both groups experienced improvement. There was no difference between the groups, however, with regard to hearing and electrocochleography (ECoG) results. The study is limited due to the difficulty in distinguishing the effect of treatment from the natural course of disease, and the authors note that it may not be possible to generalize the study results to people with variant forms of Ménière's disease.

Thomsen et al. (2005) conducted a randomized, controlled trial with primary endpoints of change in frequency of vertigo, change of functionality profile and change in patient perception of vertigo as measured on a visual analogue scale. A total of 40 patients were randomized because of noncompliance with the treatment or study protocol. The method of randomization was not reported. Patients were evaluated for two months to obtain a baseline, after which tympanostomy tubes were placed, followed by two months without treatment to account for the effect of the tympanostomy tubes. Patients then received either the Meniett device for therapy or a sham device that was identical to the active device but did not give any pressure pulses except a slight pressure increase to 2 cm H₂O for five seconds to maintain the leakage test. The authors state that the patients were unable to detect whether they were using the active or placebo device, but the basis for this statement is not discussed. Patients were evaluated at two, four, and eight weeks of use. Outcomes demonstrated significant improvement in functional level and in patient perception of vertigo in those receiving therapy with the Meniett device compared to the control group. There was a nonstatistically significant trend, toward reduced frequency of vertigo in those using the Meniett device. Study limitations include small population, exclusion of a large

number of participants, and the inability to determine whether the improvement is related to placement of the tympanostomy tube itself.

Dornhoffer et al. (2008) conducted a retrospective review on 12 patients, including nine who used the device for more than two years. Three patients showed no benefit from the Meniett and did not continue with the device. The other nine patients (75%) did perceive to have benefited from the Meniett device and thought that it had reduced the frequency, intensity, and/or duration of their vertigo attacks. Of these patients, all responded within the first four weeks, suggesting that the trial period of six weeks was adequate. The average duration of Meniett use was 47 months.

Mattox and Reichert (2008) conducted a retrospective review of 23 patients who had received the Meniett device after failing medical management for Ménière's disease. Twenty three patients were included in the review and were followed for a minimum of three years and one month to a maximum of five years and two months. Patient symptoms and continued use or disuse of the device were evaluated at two time points; at a minimum two years and at three years. At the minimum two years follow-up, two patients were lost to follow-up, and 11(52%) of the remaining 21 patients continued to use the device and reported good control of symptoms, four patients (19%) were asymptomatic at one year and discontinued using the device. The device had no effect on six patients (29%) and they had stopped using the device within three months of start of treatment. The study is limited by its retrospective design, lack of control and small sample size.

Gates et al. (2006) conducted a two-year, unblinded follow-up on participants of the Gates et al. (2004) trial. Of the original 62 participants, 58 were included in this long-term study. Primary outcomes included subjective tracking of vertigo frequency using diaries, comparison of vertigo frequency before and after Meniett device use using the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) reporting guideline, and Kaplan-Meier estimates of vertigo remission (defined as six consecutive months of no definitive vertigo attacks) and relapse (defined as two consecutive months of at least one or more definitive vertigo attacks). The AAO-HNSF results indicated 67% (39/58) had class A (remission) or B (greatly improved) results and 24% (14/58) had class F results (dropped out to receive alternative surgical treatment). Of the non-dropout cases, 89% (39/44) were classified as group A or B. Forty-three participants entered the two-year follow-up with active Ménière's disease and 15 were in remission at time of entry. Of the 43 participants with active vertigo, 20 obtained remission during the two-year follow-up. Relapse occurred in 20% (7/35) of those participants who had remitted. According to the authors, obtaining consistent data regarding vertigo frequency was difficult. They reported that those participants who used the device most had the most symptoms, whereas those participants who used the device least had the fewest symptoms. No adverse events were reported during the two-year follow-up, although there was a problem with middle ear infection associated with the tympanostomy tube use. The authors stated the use of the Meniett device for Ménière's disease may be safe and effective in the long term. Limitations of this study included small sample size, subjective reporting of data, and lack of blinding, which may indicate results due to therapy, placebo, or natural course of the disease.

Stokroos et al. (2006) performed a prospective clinical trial to evaluate the effects of Meniett on hearing threshold and labyrinthine function in 32 patients with active Ménière's disease. Labyrinthine function was determined by electronystagmography (ENG) with caloric stimulation, and hearing thresholds were determined by pure-tone audiometry. Evaluations took place at baseline before ventilation tube placement, before Meniett treatment, immediately after Meniett treatment and one month after Meniett treatment ended. Three patients exited before completion due to the effects of the ventilation tube on their Ménière's disease. The analysis showed no significant difference in hearing threshold or labyrinthine function during or after Meniett therapy. The authors concluded the Meniett device did not alter hearing or vestibular function.

Boudewyns et al. (2005) conducted a study to investigate whether Meniett therapy could be considered an option for patients referred for intratympanic gentamycin (ITG) for the treatment of drug-resistant Ménière's disease. Twelve patients referred for ITG treatment agreed to participate in the study. Symptoms, functional level, hearing status and disease-specific quality of life measures were evaluated. Patients were followed for a mean of 37 months. The Meniett device was discontinued in two patients due to severe vertigo. In the remaining 10 patients, there was a decrease in the number of vertigo spells from a median of 10 per month prior to treatment to a median of three per month after treatment. There was, however, no improvement in hearing status, tinnitus, functional level or self-perceived dizziness handicap. The long-term data (greater than one year) showed only two subjects chose to continue the Meniett therapy and that ablative surgery had to be performed in six of the 12 patients. The authors concluded that it is unlikely that long-term treatment with the Meniett

device would be successful in patients with drug-resistant Ménière's disease. This study is limited by its size and lack of comparison.

A number of uncontrolled case series were also conducted (Densert and Sass, 2001; Gates and Green, 2002; Rajan, et al., 2005). The studies suggest that treatment with the Meniett device improves functionality and decreases episodic vertigo in Ménière's patients. Subjects were followed for two years (Densert and Sass, 2001), 18 months (Rajan, et al., 2005) and for a range of 3–8 months (Gates and Green, 2002). The studies documented increases in hearing ranging from 6–63%. Additionally, the study by Densert and Sass (2001) purports to study the safety of the device and concludes that no serious side effects or adverse events were reported. Rajan et al. (2005) reported that 17% of the patients required tympanostomy tube reinsertion.

In 1997, Densert et al. documented a clinical placebo-controlled study of 39 patients with Ménière's disease. The results demonstrated statistically significant improvement in electrocochleography (ECoG) values, but the study did not correlate that improvement with improvement in the patients' condition. There was no statistical difference between the groups in symptoms or audiometric testing. In this study, improvement in ECoG values does not support the efficacy of the Meniett device in treating the symptoms of Ménière's disease.

Professional Societies/Organizations

The Equilibrium Committee of the American Academy of Otolaryngology — Head and Neck Surgery published a Policy Statement on Micropressure Therapy for Ménière's disease (2008), stating "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 Ménière'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 Ménière's disease." No bibliography was provided.

Summary

Studies supporting the use of a transtympanic micropressure device/low-pressure pulse generator for any condition including but not limited to the treatment of Ménière's disease are limited by methodological flaws, including the inability to distinguish treatment effect from that of the natural course of disease, and the inability to discern whether any improvement in symptoms is related to placement of the tympanostomy tube itself. The efficacy of the device has not been proven through well-designed trials. Prospective randomized controlled trials with sufficient sample sizes and long-term follow-up comparing transtympanic micropressure treatment to an alternative treatment, application of a sham device or to the natural course of Ménière's disease, are necessary to definitively determine the benefits of this technology in treating this condition.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Not Medically Necessary/Not Covered: when used to report tympanostomy with tube placement performed solely in preparation for the use of a transtympanic micropressure device

CPT [®] * Codes	Description
69433	Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia
69436	Tympanostomy (requiring insertion of ventilating tube), general anesthesia

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
E2120	Pulse generator system for tympanic treatment of inner ear endolymphatic fluid

ICD-9-CM Diagnosis	Description
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Codes	
386.00-386.03	Ménière's disease
	All other codes

***Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	11/15/2007	0095	Meniett™ Device
Great-West Healthcare	10/26/2006	04.265.02	Meniett Device for Treatment of Meniere's Disease

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