Transtympanic Micropressure Applications as a Treatment of Meniere Disease

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12/14/10; 12/08/09; 12/16/08; 07/10/07; 10/10/06; 10/11/05; 01/11/05; 07/13/04;
05/11/04; 01/01/04; 08/12/03
Replaces N/A

Policy

Transtympanic micropressure applications as a treatment of Meniere disease are considered not medically necessary.

Related Policies

None

Policy Guidelines

Coding

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4638</td>
<td>Replacement battery for patient-owned ear pulse generator, each</td>
</tr>
<tr>
<td>E2120</td>
<td>Pulse generator system for tympanic treatment of inner ear endolympathic fluid</td>
</tr>
</tbody>
</table>

The currently available transtympanic micropressure therapy device is The Meniett®.

Prior to use of the Meniett® device a tympanostomy procedure is required. Plans with specific medical necessity criteria for tympanostomy may be able to prospectively identify claims for the Meniett® device.

Description

For patients with Meniere disease that have failed to gain relief from conservative therapy, transtympanic micropressure treatment has been proposed as an option to treat the symptoms of vertigo and dizziness.
Background
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. 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. There has been interest in developing a more physiologic approach to treatment by applying local transtympanic pressure treatment to restore the underlying fluid homeostasis. Transtympanic micropressure treatment involves use of a handheld air pressure generator (Meniett®) that delivers intermittent complex pressure pulses.

The evidence for micropressure therapy in individuals who have Meniere disease includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Five RCTs of positive pressure therapy have been reported, with 4 trials specifically investigating the Meniett device. Systematic reviews of these trials found that micropressure therapy does not result in a greater improvement in vertigo than placebo. The evidence is sufficient to determine qualitatively that the technology is unlikely to improve the net health outcome.

Regulatory Status
In 1999, the Meniett® device (Medtronic, Minneapolis, MN) 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. The device is currently available through Meniette AG.

Scope
Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

Benefit Application
N/A

Rationale

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals: With Meniere disease</td>
<td>Interventions of interest are: • Micropressure therapy</td>
<td>Comparators of interest are: • Standard care</td>
<td>Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity</td>
</tr>
</tbody>
</table>

This policy was created in 2003 and updated periodically using the MEDLINE database. The most recent literature review was performed through December 2, 2015.

Assessment of efficacy for a therapeutic intervention involves a determination of whether the intervention improves health outcomes compared to available alternatives. The optimal study design for this purpose is a randomized controlled trial (RCT) that compares the therapeutic intervention with existing alternative treatments,
uses a placebo control, and includes clinically relevant measures of health outcomes.

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 2- to 4-year outcomes in patients who had failed medical therapy. (1-8) 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.

A 2015 Cochrane review on positive pressure therapy for Meniere disease included 5 double-blind, placebo-controlled RCTs (total N=265 patients). (9) Three of the studies were considered to be at low risk of bias, 1 was at unclear risk, and 1 study was at high risk of bias. Results on the primary outcome measure, control of vertigo, could not be pooled due to heterogeneity in measurement, but most trials showed no significant difference in vertigo between Meniett therapy and placebo. This review supports the conclusion that there is no evidence that positive pressure therapy is effective for the treatment of Meniere disease, and that there is some evidence that hearing is impaired with this treatment. Another systematic review, which included 4 of the same RCTs that specifically used the Meniett device, also found no significant difference between low pressure therapy and placebo for the frequency of vertigo. (10) The 3 trials with low risk of bias are described next.

In 2004, Gates et al. reported the 4-month results of a randomized, multi-institutional study that enrolled 67 patients with active unilateral Meniere disease refractory to a 3-month trial of medical management. (11) All patients underwent tympanostomy, and patients were additionally randomly assigned to 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 from 1 to 4, and a score of 2 or higher was considered definitive vertigo. The total number of days of definitive vertigo for all participants was reported at each month. While an analysis of variance (ANOVA) 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 with the control group, the difference between the groups was most apparent at 1 month, while at 4 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 1-month interval and almost disappeared at 4 months. This study was limited by a number of methodologic issues related to the data analysis. In particular, repeated-measures ANOVA, which was the primary statistical 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 were 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 et al. reported 2-year, open-label, follow-up from the 2004 randomized trial. (11,12) 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; 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 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. Patients who went into remission had an 80% probability of remaining in remission for the 2 years. This assessment is limited, however, by the lack of a control group followed 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. (13) This trial reported an improvement in functionality (American Academy of Otologyngology–Head and Neck Surgery 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, hearing). In addition to a marginal improvement in efficacy over ventilation tubes with sham pressure, this study was limited by a high dropout rate (37%), lack of intention-to-treat analysis, and short (2-month) monitoring period.

In 2012, Gurkov et al. reported a randomized double-blind sham-controlled trial with the Meniett device. (14) After a 4-week baseline period, 74 patients underwent ventilation tube placement and were monitored for another 4
weeks. Patients were then randomized to 16 weeks of active or sham treatment (5 minutes, 3 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 4 weeks of treatment. Sixty-eight (92%) patients 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 study showed a modest improvement in 2 of 5 subjective measures, but not in objective outcome measures, with the Meniett device. It was also limited by the relatively short (4-month) follow-up period.

**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov in January 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

**Summary of Evidence**
The evidence for micropressure therapy in individuals who have Meniere disease includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Five RCTs of positive pressure therapy have been reported, with 4 trials specifically investigating the Meniett device. Systematic reviews of these trials found that micropressure therapy does not result in a greater improvement in vertigo than placebo. The evidence is sufficient to determine qualitatively that the technology is unlikely to improve the net health outcome.

**Clinical Input Received 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. Clinical 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 (AAO-HNS)*
In 2012, AAO-HNS 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 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." (15) No supporting evidence was provided.

*National Institute for Clinical Excellence (NICE)*
In 2012, guidance from the United Kingdom’s NICE concluded that current evidence on the safety of micropressure therapy for refractory Meniere 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. (16)

**U.S. Preventive Services Task Force Recommendations**
N/A

**Medicare National Coverage**
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the
discretion of local Medicare carriers.

References


Appendix

N/A

History
<table>
<thead>
<tr>
<th>Date</th>
<th>Reason</th>
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<td>08/12/03</td>
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<td>11/10/11</td>
<td>Replace policy – Policy updated with literature search through July 2011; policy statement unchanged. Title changed; &quot;Menett® Device&quot; removed.</td>
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<td>08/24/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/14/2014.</td>
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<td>12/19/12</td>
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<td>12/09/13</td>
<td>Replace policy. Policy updated with literature search through August 26, 2013; policy statement unchanged. CPT codes 69433 and 69436 removed from the policy as they do not apply.</td>
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<td>12/17/14</td>
<td>Annual Review. Policy updated with literature review through August 28, 2014; no new references added. Minor edits for readability. Policy statement unchanged. ICD-9 and ICD-10 diagnosis codes removed; these do affect administration of the policy.</td>
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<td>12/08/15</td>
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<tr>
<td>04/12/16</td>
<td>Annual Review. Policy updated with literature review through December 2, 2015; references 9-10 added. Policy statement changed to not medically necessary.</td>
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Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA).

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U. S. Department of Health and Human Services
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Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
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Deutsche (German):


Iloko (Ilocano):

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