Introduction

Meniere disease is a condition affecting the inner ear that makes the person feel like they are spinning (vertigo). They may also have ringing in their ears and intermittent hearing loss, but eventually the hearing loss becomes permanent. Meniere disease usually happens in adults younger than 50. There is no cure for Meniere disease, and it has been mostly treated with medications.

A “transtympanic micropressure application” device (called a Meniett device) is a new treatment that is thought to help the symptoms of Meniere disease. The device is placed in the ear canal several times a day and puts a tiny amount of pressure on the inner ear. This treatment is supposed to help relieve the symptoms of Meniere disease. Medical studies have not shown that the device is safe and effective. For this reason, transtympanic micropressure application devices are considered not medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transtympanic</td>
<td>Transtympanic micropressure applications as a treatment of Meniere disease are considered not medically necessary.</td>
</tr>
<tr>
<td>micropressure applications</td>
<td></td>
</tr>
</tbody>
</table>

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<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 endolymphatic fluid</td>
</tr>
</tbody>
</table>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

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.

Evidence Review

Description

Meniere 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,
incapacitating, and may impede activities of daily living. Therapy addresses symptoms, not the underlying pathophysiology. Although the pathophysiology of Meniere 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 (ie, hydrops) and pharmacologic therapy to reduce vestibular symptoms. Persons who do not respond to these conservative measures may receive gentamicin in the middle ear, as a technique of chemical labyrinthectomy to ablate vestibular function on the affected side. No therapy is available to restore hearing loss.

Background

There has been interest in developing a more physiologic approach to treatment by applying local transtympanic pressure treatment to restore the underlying fluid homeostasis. Researchers have noted that symptoms of Meniere 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. Transtympanic micropressure treatment for Meniere disease involves use of a handheld air pressure generator (Meniett) 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 continues for as long as patients have vertigo attacks.

Summary of Evidence

For individuals who have Meniere disease who receive transtympanic micropressure therapy (Meniett), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Six RCTs of positive pressure therapy have been reported, with 5 trials specifically investigating the Meniett device. A systematic reviews of 5 of these trials found that micropressure therapy does not result in a greater reduction in vertigo than placebo. The sixth trial also found no significant benefit of the transtympanic micropressure therapy for Meniere disease. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.
Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in January 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, 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 2016, the American Academy of Otolaryngology – Head and Neck Surgery updated its position statement on the use of transtympanic micropressure:

We find that there is some 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.\(^{16}\)

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.17

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.

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.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/12/03</td>
<td>Add to Durable Medical Equipment - New Policy</td>
</tr>
<tr>
<td>01/01/04</td>
<td>Replace policy - HCPC code updates only.</td>
</tr>
<tr>
<td>05/11/04</td>
<td>Replace policy - Policy reviewed; policy guidelines updated.</td>
</tr>
<tr>
<td>07/13/04</td>
<td>Replace policy - Policy reviewed with literature review; no new literature; no change to policy statement.</td>
</tr>
<tr>
<td>01/11/05</td>
<td>Replace policy - Policy updated with literature and review of randomized study. Reference added; no change in policy statement.</td>
</tr>
<tr>
<td>10/11/05</td>
<td>Replace policy - Policy updated with literature search; no changes in policy statement.</td>
</tr>
<tr>
<td>05/26/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>----------</td>
</tr>
<tr>
<td>10/10/06</td>
<td>Replace policy - Policy updated with literature search; references added; policy statement remains unchanged. Title expanded to name Meniett® Device as title header.</td>
</tr>
<tr>
<td>07/10/07</td>
<td>Replace policy - Policy updated with literature search; references added; no change in policy statement</td>
</tr>
<tr>
<td>12/11/07</td>
<td>Cross Reference Updated - No other changes.</td>
</tr>
<tr>
<td>12/16/08</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. References added.</td>
</tr>
<tr>
<td>12/08/09</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. Reference added.</td>
</tr>
<tr>
<td>12/14/10</td>
<td>Replace policy - Policy updated with literature search through July 2010; no change in policy statement.</td>
</tr>
<tr>
<td>11/10/11</td>
<td>Replace policy – Policy updated with literature search through July 2011; policy statement unchanged. Title changed; “Meniett® Device” removed.</td>
</tr>
<tr>
<td>08/24/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/14/2014.</td>
</tr>
<tr>
<td>12/19/12</td>
<td>Replace policy. Policy updated with literature search through August 2012; references 12 and 14 added; policy statement unchanged.</td>
</tr>
<tr>
<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>
</tr>
<tr>
<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>
</tr>
<tr>
<td>12/08/15</td>
<td>Annual Review. References 15 and 16 added. No change to policy statement.</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Annual Review, changes approved April 12, 2016. Policy updated with literature review through December 2, 2015; references 9-10 added. Policy statement changed to not medically necessary.</td>
</tr>
<tr>
<td>05/01/17</td>
<td>Annual review, changes approved April 11, 2017. Policy updated with literature review through December 9, 2016; reference 15 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>09/22/17</td>
<td>Policy moved into new format; no change to policy statements.</td>
</tr>
</tbody>
</table>

**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.
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.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
 Toll free 855-332-4535, Fax 425-918-5992. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at http://www.hhs.gov/ocr/office/file/index.html.

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.
Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Amharic):

لا تقبل Premera Blue Cross الالتباس بprémera. يجوز لك الحصول على المعلومات المذكورة أعلاه باللغة التي ت fseek فيها. طلبك عاجل، ولكن من الضروري تقديم الوثائق والمستندات المذكورة أعلاه في هذا التاريخ. قد تحتاج إلى تقديم إثبات وظيفتك من نوع معين للحصول على معلومات المعايير الصحية والمساعدة في ذلك. يطلب منك تقديم جملة متعلقة بموضوعك على الخط الأزرق خلال 800-722-1471 (TTY: 800-842-5357) مجانًا.

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健保保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請接電話 800-722-1471 (TTY: 800-842-5357)。

Oromoo (Cushite):


Français (French):


Deutsche (German):


Italiano (Italian):

Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring ito ay maaaring naglalaman ng mahalagang impormasyon.

Vielen Dank (German): Dieser Aufsatz beinhaltet wichtige Informationen. Bitte prüfen Sie die Dokumente, die Ihnen mitgegeben wurden.

İşverenler (Turkish): Bu yazıda önemli bilgiler bulunmaktadır. Lütfen verdiğiniz belgeleri kontrol edin.

Primažno zaključno pozdravilo (Slovene): To je bil pomembno opozorilo, ki vključujejo pomembne informacije. Prosimo, preglejte vse dodatne dokumente, ki jih je vam vlagal.

Capablen (Swahili): Hii ni dharmlilioni muhimu kuhusu Premera Blue Cross. Hivyo, basi unaweza kusimamia makao za ujumlaa zaidi kuhusu Premera Blue Cross.

Русский (Russian): В этом письме содержатся важные сведения. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross.


Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring ito ay maaaring naglalaman ng mahalagang impormasyon.

Português (Portuguese): Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir dados importantes neste aviso.
