



BlueCross BlueShield  
of Alabama

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**Name of Blue Advantage Policy:**

**Transtympanic Micropressure Applications as a Treatment of Ménière's Disease**

Policy #: 092  
Category: DME

Latest Review Date: February 2020  
Policy Grade: **Effective March 17, 2020: Active policy but no longer scheduled for regular literature reviews and updates.**

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**BACKGROUND:**

*Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational\*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
  - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
  - *Furnished in a setting appropriate to the patient's medical needs and condition;*
  - *Ordered and furnished by qualified personnel;*
  - *One that meets, but does not exceed, the patient's medical need; and*
  - *At least as beneficial as an existing and available medically appropriate alternative.*

*\*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare** for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

## **POLICY:**

**Effective for dates of service on or after July 1, 2005:**

**Blue Advantage will treat Transtympanic micropressure applications as a treatment of Ménière's disease as a non-covered benefit and as investigational.**

*Blue Advantage 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 Advantage administers benefits based on the members' contract and 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.*

## **DESCRIPTION OF PROCEDURE OR SERVICE:**

Meniere's 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 (i.e., hydrops) and pharmacologic therapy to reduce vestibular symptoms. Transtympanic pressure treatment has been proposed as an alternative treatment for Meniere disease. This treatment involves use of a handheld device (e.g., Meniett) that delivers air pressure pulses to the ear.

### **Meniere Disease**

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.

### **Treatment**

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.

Transtympanic micropressure treatment for Meniere's 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 is continued for as long as patients find themselves in a period of attacks of vertigo.

## **KEY POINTS:**

The most recent literature review was updated through November 27, 2019.

### **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.

### **Practice Guidelines and Position Statements:**

#### **American Academy of Otolaryngology-Head and Neck surgery**

In 2016, the American Academy of Otolaryngology-Head and Neck Surgery updated their 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'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.

#### **National Institute for Clinical Excellence (NICE)**

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.

#### **U.S. Preventive Services Task Force Recommendations:**

Not applicable.

## **KEY WORDS:**

Meniere's disease, Meniett, low-pressure pulse generator, transtympanic micropressure

## **APPROVED BY GOVERNING BODIES:**

In 1999, the Meniett® device (Medtronic Xomed, Inc., Jacksonville, Florida) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510 (k) process as a symptomatic treatment of Meniere's disease.

## **BENEFIT APPLICATION:**

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

## **CURRENT CODING:**

HCPCS codes:

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| <b>A4638</b> | Replacement battery for patient owned ear pulse generator, each            |
| <b>E2120</b> | Pulse generator system for tympanic treatment of inner endolymphatic fluid |

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## **POLICY HISTORY:**

Adopted for Blue Advantage, March 2005

Available for comment May 1-June 14, 2005

Medical Policy Group, September 2006

Medical Policy Group, September 2008

Medical Policy Group, September 2010

Medical Policy Group, October 2011

Medical Policy Group, October 2012

Medical Policy Group, October 2013

Medical Policy Group, October 2014

Medical Policy Group, February 2016

Medical Policy Group, February 2017

Medical Policy Group, July 2017

Medical Policy Group, February 2018

Medical Policy Group, February 2019

Medical Policy Group, February 2020

Medical Policy Group, March 2020: Effective March 17, 2020: Active policy but no longer scheduled for regular literature reviews and updates.

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*