Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Transtympanic Micropressure Applications as a Treatment of Ménière's Disease

Policy #: 092
Latest Review Date: August 2023
Category: DME
ARCHIVED EFFECTIVE 11/1/2023

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:

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 micropressure 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.

Treatment

Conservative therapy includes a low sodium diet and diuretics to reduce fluid accumulation (i.e., hydrops) and pharmacologic therapy to reduce vestibular symptoms. Individuals 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 individuals 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. Individuals 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 of the PubMed database was updated through August 23, 2023.

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 2020, the American Academy of Otolaryngology-Head and Neck Surgery published their Clinical Practice Guideline: Ménière's Disease.

- The purpose of this statement is to discourage the use of the positive pressure–generating devices such as the Meniett device for MD. These devices are considered minimally invasive, as they deliver small pressure pulses to the inner ear via an earpiece placed in the external ear canal. A tympanostomy tube (placed in the eardrum) allows the micropulses to enter the middle ear space, where it then transfers the pressure to the inner ear, resulting in a displacement of the excess inner ear fluid (endolymph), theoretically resulting in "normal" inner ear pressure.
- STATEMENT 10. POSITIVE PRESSURE THERAPY: Clinicians should not prescribe positive pressure therapy to patients with Ménière's disease. Recommendation against based on a systematic review and randomized trials showing ineffectiveness of devices like the Meniett devices with a preponderance of benefit over harm for not using.

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.

- 1.1 Current evidence on the safety of micropressure therapy for refractory Ménière's disease is inadequate in quantity. There is some evidence of efficacy, but 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.
- 1.3 NICE encourages further research into micropressure therapy for refractory Ménière's disease. Research studies should report long-term outcomes, in particular the need for subsequent surgical treatment.

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 Minneapolis, MN) 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:

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

REFERENCES:

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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
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Medical Policy Group, October 2011
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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
Medial 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.
Medical Policy Group, August 2021
Medical Policy Group, August 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, August 2023
Medical Policy Group, November 2023: Archived effective 11/1/2023.
