



Geisinger Health Plan Policies and Procedure Manual

Policy: MP176

Section: Medical Benefit Policy

Subject: Meniett™ Device

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Meniett™ Device

II. Purpose/Objective:

To provide a policy of coverage regarding Meniett™ Device

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

The Meniett™ Device (e.g. Transtympanic Micropressure), an aural low-pulse pressure generator, is used to deliver low frequency, low-amplitude pressure pulses to the middle ear through a close fitting ear cuff and a previously placed tympanostomy tube. Although the precise mechanism of the Meniett™ Device is unknown, it is hypothesized that the transmission of the pulses to the inner ear promotes the flow of the endolymph out of the cochlea, which alleviates the hydrops and relieves symptoms. The treatment is self-administered three times daily, consisting of 3 cycles (1 minute of pressure pulses and 40 seconds of pause) per treatment. Each treatment lasts approximately 5 minutes, and an entire month of daily treatment is needed to determine if it is appropriate for the patient.

EXCLUSIONS: The Plan does **NOT** provide coverage for use of an aural low-pulse pressure generator (e.g. Transtympanic Micropressure) (i.e. Meniett™ Device) as a treatment for Meniere's disease because it is considered **experimental, investigational or unproven**. Although the device is FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Meniett™ Device

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

E2120 Pulse generator system for tympanic treatment of inner ear, endolymphatic fluid

A4638 Replacement battery for patient-owned ear pulse generator, each

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

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

ECRI, HTAIS Target database (online), Transtympanic Micropressure Treatment for Meniere's disease. Updated March 2005.

Winifred S. Hayes, Hayes INC. (online) Meniett Device for Treatment of Meniere's disease. April 2003.

Rajan GP, Din S, Atlas MD. Long-term effects of the Meniett device in Meniere's disease: the Western Australian experience. J Laryngol Otol 2005 May;119:391-395.

Thomsen J, Sass K, Odkvist L, Arlinger S. Local overpressure treatment reduces vestibular symptoms in patients with Meniere's disease: a clinical, randomized, multicenter, double-blind, placebo-controlled study. Otol Neurotol. 2005 Jan;26(1):68-73.

Barbara M, Consagra C, Monini S, Nostro G, Harguindey A, Vestri A, Filippo R. Local pressure protocol, including Meniett, in the treatment of Meniere's disease: short-term results during the active stage. Acta Otolaryngol 2001 Dec;121(8):939-44.

Gates GA, Green Jr. JD, Tucci DL, Telian SA. The effects of transtympanic micropressure treatment in people with unilateral Meniere's disease. *Arch Otolaryngol Head Neck Surg.* 2004; 130:718-725.

Medtronic Xomed, Inc. (website) Jacksonville Fl. Meniett™ Device;2005 Accessed on February 24, 2006 at <http://www.meniett.com>

Odkvist LM, Arlinger S, Billermark E, Densert B, Lindholm S, Wallqvist J. Effects of middle ear pressure changes on clinical symptoms in patients with Meniere's Disease- a clinical multicenter placebo controlled study. *Acta Otolaryngol* 2000; Suppl 543:99-101.

Odkvist LM. Pressure treatment versus gentamicin for Meniere's disease. *Acta Otolaryngol* 2001;121:266-268.

Densert B, Sass K. Control symptoms in patients with Meniere's disease using middle ear pressure applications: Two years follow-up. *Acta Otolaryngol* 2001;121:616-621.

Stokroos R, Klein Olivink M, Hendrice N, Kingma H. Functional outcome of treatment of Meniere's disease with the Meniett pressure generator. *Otolaryngol.* 2006 Mar;126(3):254-8.

Dornhoffer JL, King D. The effect of the Meniett device in patients with Ménière's disease: long-term results. *Otol Neurotol.* 2008 Sep;29(6):868-74.

American Academy of Otolaryngology—Head and Neck Surgery. Meniere's disease. Accessed September 2009. Available at URL address: <http://www.entnet.org/HealthInformation/menieresDisease.cfm>

Ahsan SF, Standing R, Wang Y. Systematic review and meta-analysis of Meniett therapy for Meniere's disease. *Laryngoscope.* 2015; 125(1):203-208

Syed MI, Rutka J, Hendry J, Browning GG. Positive pressure therapy for Meniere's syndrome/ disease with a Meniett device: A systematic review of randomised controlled trials. *Clin Otolaryngol.* 2015;40(3):197-207.

van Sonsbeek S, Pullens B, van Benthem PP. Positive pressure therapy for Meniere's disease or syndrome. *Cochrane Database Syst Rev.* 2015;3:CD008419.

Russo FY, Nguyen Y, De Seta D, et al. Meniett device in Meniere disease: Randomized, double-blind, placebo-controlled multicenter trial. *Laryngoscope.* Feb 2017;127(2):470-475.

Shojaku H, Takakura H, Asai M, Fujisaka M, Ueda N, Do TA, Tsubota M, Watanabe Y. Long-term effect of transtympanic intermittent pressure therapy using a tympanic membrane massage device for intractable meniere's disease and delayed endolymphatic hydrops. *Acta Otolaryngol.* 2021 Nov;141(11):977-983

Shojaku H, Aoki M, Takakura H, Fujisaka M, Asai M, Tsubota M, Ito Y, Watanabe Y. Effects of transtympanic intermittent pressure therapy using a new tympanic membrane massage device for intractable Meniere's disease and delayed endolymphatic hydrops: a prospective study. *Acta Otolaryngol.* 2021 Oct;141(10):907-914.

This policy will be revised as necessary and reviewed no less than annually.

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Reviewed: 03/07, 3/08, 3/09, 3/10, 3/12, 3/13, 3/14, 3/15, 3/16, 2/17, 2/18, 2/19, 2/20, 2/21, 2/22, 2/23

CMS UM Oversight Committee Approval: 12/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.