MEDICAL POLICY

POLICY TITLE	TREATMENT OF MENIERE'S DISEASE AND SUDDEN HEARING LOSS
POLICY NUMBER	MP 1.095

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**3/1/2024**

I. POLICY

Intratympanic dexamethasone for the treatment of Meniere's disease and sensorineural hearing loss, hearing loss from autoimmune disease (e.g., Cogan syndrome) and other inflammatory inner ear diseases may be considered **medically necessary**.

Transtympanic micropressure applications as a treatment of Meniere's disease are considered **not medically necessary**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP 2.103 Off-Label Use of Medications
MP 2.070 Hyperbaric Oxygen Therapy (HBO)

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO: Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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Meniere's Disease
Meniere's 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's 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 (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. No therapy is available to restore hearing loss.

There has been interest in developing a more physiologic treatment approach by applying local transtympanic pressure 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 the 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.

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

IV. RATIONALE

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Summary of Evidence
For individuals who have Meniere's disease who receive transtympanic micropressure therapy (Meniett), the evidence includes 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 five specifically investigating the Meniett device. Systematic reviews of these 5 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's 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 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'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.

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS):

AAO-HNS published a clinical practice guideline for Ménière's disease in April 2020. The guidelines include discussion regarding 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."

The guideline also speaks to intratympanic steroid therapy, stating that "Clinicians may offer, or refer to a clinician who can offer, intratympanic (IT) steroids to patients with active Ménière's disease not responsive to noninvasive treatment. Option based on a systematic review and a randomized controlled trial with a preponderance of benefit over harm."

In August 2019, the AAO-HNS published an update to the clinical practice guideline for Sudden Hearing Loss. The recommendation states "Clinicians should offer, or refer to a clinician who can offer, IT steroid therapy when patients have incomplete recovery from SSNHL 2 to 6 weeks after onset of symptoms. Recommendation based on systematic reviews of RCTs with a preponderance of benefit over harm."

National Institute for Health and Care Excellence
In 2012, guidance from the U.K.'s National Institute for Health and Care Excellence concluded that "[c]urrent 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…."

V. DEFINITIONS

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ENDOLYMPH -2/13/2024 pale fluid in the membranous labyrinth (cochlear duct) of the internal ear.
INTRATYMPANIC - within the tympanic cavity.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Not medically necessary; therefore not covered, transtympanic micropressure applications as treatment of Meniere's disease:

Procedure Codes								
A4638	E2120	69799						

Covered when medically necessary, intratympanic dexamethasone for treatment of Meniere's disease and sensorineural hearing loss, hearing loss from autoimmune disease (e.g., Cogan Syndrome), and other inflammatory inner ear diseases:

Procedure Codes								
J1094	J1100	69801						

ICD-10-CM Diagnosis Codes	Description
H81.01	Meniere's disease, right ear
H81.02	Meniere's disease, left ear
H81.03	Meniere's disease, bilateral
H81.09	Meniere's disease, unspecified
H83.01	Labyrinthitis, right ear
H83.02	Labyrinthitis, left ear
H83.03	Labyrinthitis, bilateral
H83.09	Labyrinthitis, unspecified
H90.3	Sensorineural hearing loss, bilateral

H90.41	Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.42	Sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
H90.5	Unspecified sensorineural hearing loss
H90.6	Mixed conductive and sensorineural hearing loss, bilateral
H90.71	Mixed conductive and sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.72	Mixed conductive and sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
H90.8	Mixed conductive and sensorineural hearing loss, unspecified
H90.A21	Sensorineural hearing loss, unilateral, right ear, with restricted hearing on the contralateral side
H90.A22	Sensorineural hearing loss, unilateral, left ear, with restricted hearing on the contralateral side
H90.A31	Mixed conductive and sensorineural hearing loss, unilateral, right ear with restricted hearing on the contralateral side
H90.A32	Mixed conductive and sensorineural hearing loss, unilateral, left ear with restricted hearing on the contralateral side

IX. REFERENCES

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1. *U.S. Food and Drug Administration (FDA). FDA 510(k) marketing clearance information for the Meniett device (K991562). 1999;.*
2. *Barbara M, Consagra C, Monini S, et al. Local pressure protocol, including Meniett, in the treatment of Meniere's disease: short-term results during the active stage. Acta Otolaryngol. Dec 2001;121(8):939-944. PMID 11813899*
3. *Densert B, Sass K. Control of symptoms in patients with Meniere's disease using middle ear pressure applications: two years follow-up. Acta Otolaryngol. Jul 2001;121(5):616-621. PMID 11583396*
4. *Gates GA, Green JD, Jr. Intermittent pressure therapy of intractable Meniere's disease using the Meniett device: a preliminary report. Laryngoscope. Aug 2002;112(8 Pt 1):1489-1493. PMID 12172267*
5. *Barbara M, Monini S, Chiappini I, et al. Meniett therapy may avoid vestibular neurectomy in disabling Meniere's disease. Acta Otolaryngol. Nov 2007;127(11):1136-1141. PMID 17851896*
6. *Dornhoffer JL, King D. The effect of the Meniett device in patients with Meniere's disease: long-term results. Otol Neurotol. Sep 2008;29(6):868-874. PMID 18617868*
7. *Mattox DE, Reichert M. Meniett device for Meniere's disease: use and compliance at 3 to 5 years. Otol Neurotol. Jan 2008;29(1):29-32. PMID 18199955*
8. *Park JJ, Chen YS, Westhofen M. Meniere's disease and middle ear pressure: vestibular function after transtympanic tube placement. Acta Otolaryngol. Dec 2009;129(12):1408-1413. PMID 19922090*

9. *van Sonsbeek S, Pullens B, van Benthem PP. Positive pressure therapy for Meniere's disease or syndrome. Cochrane Database Syst Rev. Mar 10 2015;3(3):CD008419. PMID 25756795*
10. *Syed MI, Rutka JA, Hendry J, et al. Positive pressure therapy for Meniere's syndrome/disease with a Meniett device: a systematic review of randomised controlled trials. Clin Otolaryngol. Jun 2015;40(3):197-207. PMID 25346252*
11. *Gates GA, Green JD, Jr., Tucci DL, et al. The effects of transtympanic micropressure treatment in people with unilateral Meniere's disease. Arch Otolaryngol Head Neck Surg. Jun 2004;130(6):718-725. PMID 15210552*
12. *Gates GA, Verrall A, Green JD, Jr., et al. Meniett clinical trial: long-term follow-up. Arch Otolaryngol Head Neck Surg. Dec 2006;132(12):1311-1316. PMID 17178941*
13. *Thomsen J, Sass K, Odkvist L, et al. Local overpressure treatment reduces vestibular symptoms in patients with Meniere's disease: a clinical, randomized, multicenter, double-blind, placebo-controlled study. Otol Neurotol. Jan 2005;26(1):68-73. PMID 15699722*
14. *Gurkov R, Filipe Mingas LB, Rader T, et al. Effect of transtympanic low-pressure therapy in patients with unilateral Meniere's disease unresponsive to betahistine: a randomised, placebo-controlled, double-blinded, clinical trial. J Laryngol Otol. Apr 2012;126(4):356-362. PMID 22365373*
15. *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. PMID 27515294*
16. *American Academy of Otolaryngology - Head and Neck Surgery. Position statement: micropressure therapy. 2016;..*
17. *National Institute for Health and Care (NICE). Micropressure therapy for refractory Ménière's disease [IPG426]. 2012;. https://www.nice.org.uk/guidance/IPG426 . Accessed January 5,2022*
18. *American Academy of Otolaryngology - Head and Neck Surgery. Meniere's disease. 2014;..*
19. *Chandrasekhar, S. S., Tsai Do, B. S., Schwartz, S. R., Bontempo, L. J., Faucett, E. A., & Finestone, S. A. (2019, August 1). Clinical practice guideline: Sudden hearing loss (update). Otolaryngology-Head and Neck Surgery.*
20. *Basura, G. J., Adams, M. E., Monfared, A., Schwartz, S. R., Antonelli, P. J., Burkard, R., Bush, M. L., & Bykowski, J. (2020, April 8). Clinical practice guideline: Ménière's disease - wiley online library. Otolaryngology- Head and Neck Surgery.*
21. *Archived: Blue Cross Blue Shield Association Medical Policy Reference Manual. 1.01.23, Transtympanic Micropressure Applications as a Treatment of Meniere Disease. April 2020 (Archived).*

Other Sources

1. *Mosby's Medical, Nursing, & Allied Health Dictionary, 6th edition.*
2. *Rauch SD, Halpin CF, et al. Oral vs Intratympanic Corticosteroid Therapy for Idiopathic Sudden Sensorineural Hearing. JAMA May 25, 2011, Vol 305, No. 20 .*
3. *Taber's Cyclopedic Medical Dictionary, 20th edition.*
4. *The Meniett Device [Website] www.meniett.com. Accessed January 5, 2022.*

5. *Moskowitz H. Meniere disease: Evaluation, diagnosis and management: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated October 18, 2021..*

X. POLICY HISTORY

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MP 1.095	**CAC 9/30/03**
	CAC 4/26/05
	CAC 3/28/06
	CAC 3/27/07
	CAC 3/25/08 Consensus review
	CAC 5/26/09 Consensus review
	CAC 7/27/10 Consensus review
	CAC 7/26/11 Consensus review
	CAC 8/28/12 Consensus review. No change to policy statements. References updated Codes reviewed 8/22/12
	3/4/13 Admin Update. Medically necessary codes added, ICD-10 codes and ICD-9 codes added
	CAC 3/26/13 Minor review. FEP variation added to reference MP-1.01.23 Transtympanic Micropressure Applications as a Treatment of Meniere's Disease. Changed use of intratympanic dexamethasone for the treatment of Meniere's disease and sensorineural hearing loss, hearing loss from autoimmune disease (e.g., Cogan syndrome) and other inflammatory inner ear diseases from investigational to medically necessary. Codes reviewed 11/29/2012. Dexamethasone removed 12/10/12
	CAC 1/28/14 Consensus review. No change to policy statements. References updated
	CAC 1/27/15 Consensus review. No change to policy statements. References updated. Rationale added. Codes reviewed.
	CAC 3/29/16 Minor review. Changed policy statement indicating Transtympanic micropressure applications as a treatment of Meniere's disease is not medically necessary. Was investigational. Updated references and rationale. Coding updated.
	11/15/16 Admin Update. Variation Reformatting
	1/1/17 Admin Update. New diagnosis codes H90.A21 and H90.A22 added effective 10/1/2016
	CAC 3/28/17 Consensus review. No changes to the policy statement. References reviewed. Policy reviewed. Coding reviewed.
	2/26/18 Consensus review. No change to policy statements. Background, rationale and references updated.
	4/15/19 Admin coding update. Diagnoses updated.
	4/18/19 Consensus review. Policy statements unchanged. References updated.

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	4/23/20 Consensus review. Policy statements unchanged. Table reformatted. References updated.
	8/12/2021 Consensus review. Policy statement unchanged. References and coding reviewed.
	1/05/2022 Consensus review. Policy statement unchanged. Coding reviewed. Rationale updated to just include summary and new guidelines. References updated.
	8/11/2023 Consensus review. Policy statement unchanged. Updated rationale with guideline information. Updated references and coding tables. Coding reviewed, no changes.
	1/19/2024 Administrative update. Clinical benefit added.

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