

MEDICAL POLICY

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

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| CLINICAL BENEFIT | <input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE. |
| Effective Date: | 4/1/2025 |

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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,

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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 (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 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

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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 “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....”

V. DEFINITIONS

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ENDOLYMPH: 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 are based on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. Members and providers should consult the member’s health benefit plan for information or contact Capital Blue Cross for benefit information.

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VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits. These medical policies 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 | | | | | | | | |
|-----------------|-------|--|--|--|--|--|--|--|
| 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 |

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| 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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| MP 1.095 | 04/23/2020 Consensus Review. Policy statements unchanged. Table reformatted. References updated. |
| | 08/12/2021 Consensus Review. Policy statement unchanged. References and coding reviewed. |
| | 01/05/2022 Consensus Review. Policy statement unchanged. Coding reviewed. Rationale updated to just include summary and new guidelines. References updated. |
| | 08/11/2023 Consensus Review. Policy statement unchanged. Updated rationale with guideline information. Updated references and coding tables. Coding reviewed, no changes. |
| | 01/19/2024 Administrative Update. Clinical benefit added. |
| | 05/31/2024 Consensus Review. Policy statement unchanged. Reviewed and updated references. |
| | 3/11/2025 Administrative Update. Removed deleted code J1094 effective 04/01/2025. |

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