Medica Coverage Policy

<table>
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<tr>
<th>Policy Name:</th>
<th>Meniet™ Portable Pulse Generator for Treatment of Meniere’s Disease</th>
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<td>Effective Date:</td>
<td>5/20/2019</td>
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Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

The Meniet™ portable pulse generator for treatment of Meniere’s disease is investigative and unproven and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: This policy is no longer scheduled for routine review of the scientific literature.

Description

Meniere’s disease is characterized by an excess build-up of fluid and pressure in the inner ear, specifically in the endolymph tissue. Patients may experience vertigo, hearing loss, and/or ringing and a feeling of fullness in the ears. Standard treatment of Meniere’s disease includes dietary restrictions and/or medical management. Patients who have failed standard treatment might undergo surgical intervention. Established surgical options include endolymphatic shunt placement, vestibular nerve section, or labyrinthectomy.

The Meniett device is considered an alternative to established surgical options. Treatment consists of two phases. First, two weeks prior to initiation of treatment, a conventional ventilation tube is surgically placed in the eardrum between the external canal and the middle ear. The technique and supplies used are identical to that of ventilation placement for other indications, such as otitis media.

The Meniett device is a portable, tabletop, air pressure therapy unit intended for home use. After inserting an ear cuff in the external ear canal, low frequency, low-amplitude, computer-generated pressure pulses are administered through the ventilation tube. Although the exact mechanism of action is not known, it is postulated that the air pulses increase pressure within the middle ear, thus reducing fluid pressure within the inner ear.
Recommended treatment is three, five-minute daily sessions. Each session consists of three cycles; each cycle includes one minute of pressure-pulse administration followed by a 40-second pause. Four to five weeks of treatment is usually needed in order to ascertain effectiveness of treatment. Treatment continues for as long as the patient is experiencing an episode of vertigo or related symptoms. During periods of remission, treatment is not needed.

**FDA Approval**
The FDA approved the Meniett device (Medtronic Xomed) for marketing in 1999 as a class II device. The Meniett device is indicated for treatment of symptoms associated with Meniere’s disease.

**Prior Authorization**
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

**Coding Considerations**
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

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

Original Effective Date: 3/1/2004
Re-Review Date(s): 1/23/2007
- 2/29/2010
- 3/20/2013
- 2/17/2016
- 2/20/2019
- 2/20/2020 – administrative update; format